REFINITIV

DELTA REPORT

10-K

ROCKWELL MEDICAL, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4375
CHANGES	243
DELETIONS	1882
ADDITIONS	2250

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022 December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**38-3317208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
30142 S. Wixom Road, Wixom, Michigan	**48393**
(Address of principal executive offices)	(Zip Code)

(248) 960-9009
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Trading Symbol(s):**	**Name of each exchange on which registered:**
Common Stock, par value $.0001	RMTI	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:
(None)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2022 June 30, 2023 (computed by reference to the closing sales price of the registrant's Common Stock as reported on The Nasdaq Capital Market on such date) was $11,096,662. $91,048,814.

Number of shares outstanding of the registrant's Common Stock, par value $0.0001, as of March 29, 2023 March 21, 2024: 12,552,673 29,334,617 shares.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement pertaining to the 2023 2024 Annual Meeting of Stockholders, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year ended December 31, 2022 December 31, 2023, are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

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Forward Looking Statements

We make, or incorporate by reference, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, in this Annual Report on Form 10-K. All statements other than statements of historical fact are forward-looking statements.Our forward-looking statements are subject to risks and uncertainties and include information about our current expectations and possible or assumed future results of our operations. When we use words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast,"

"projected," "project," "intend," or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our liquidity and capital resources; our ability to continue as a going concern; our ability to develop ferric pyrophosphate citrate ("FPC") for other indications; successfully integrate acquisitions; our ability to raise additional capital; our ability to successfully implement certain cost containment and cost-cutting measures; our ability to achieve profitability; our ability to successfully execute on our business strategy and development of new indications; strategy; and statements regarding our anticipated future financial condition, operating results, cash flows and business plans. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different from the anticipated future results, performance or achievements expressed or implied by any forward-looking statements. Such business, economic and competitive uncertainties include:

- any further increases in raw material, labor, fuel or other input costs, particularly if we are unable to pass these cost increases along to our customers;
- our ability to negotiate favorable agreements with major customers and obtain and/or retain major customers and distributors;
- the duration over which our cash balances will fund our operations;
- our ability to continue as a going concern;
  - our ability to grow our revenue generating business;
- our expectations for generating revenue or becoming profitable on a sustained basis;
- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities;
- our expectations regarding our ability to enter into marketing and other partnership agreements, including amendments to our existing agreements;
- our ability to comply with affirmative and negative covenants under our Loan Agreement with Innovatus;
- the effects of the COVID-19 pandemic macroeconomic conditions, geopolitical events and pandemics on patients, our customers and distributors, and our business, including manufacturing operations and suppliers;
  - the acceptance of our products by doctors, patients or payors;
- the availability of adequate reimbursement for our products from insurance companies and the government;
- our ability to use existing inventory before shelf life expiration;
- the safety and efficacy of our products;
- our expectations regarding the timing of submissions to, and decisions made by, the U.S. Food and Drug Administration ("FDA"), and other regulatory agencies, including foreign regulatory agencies;
- our ability to secure adequate protection for, and licensure of, our intellectual property;
  - our estimates regarding the capacity of manufacturing and other facilities to support our products;
- our ability to successfully commercialize our products;
- the rate and degree of market acceptance and clinical utility of our products;
- our ability to compete against other companies and research institutions; companies;
- our ability to attract and retain key personnel;
- our expectations for increases or decreases in expenses;
- our expectations for incurring capital expenditures to expand our manufacturing and research and development capabilities;

- our expectations regarding the effect of changes in accounting guidance or standards on our operating results;
- the impact of any cybersecurity breaches or cyber crime that we, our vendors or our customers may experience;
- the impact of healthcare reform laws and other government laws and regulations;
- the impact of potential shareholder activism;
- our ability to comply with the covenants included in the Products Purchase Agreement, as amended, and the profitability of such agreement; and
- those factors identified in this Annual Report on Form 10-K under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in other filings we periodically make with the SEC.

You should evaluate all forward-looking statements made in this Annual Report on Form 10-K, including the documents we incorporate by reference, in the context of these risks, uncertainties and other factors. Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flows, business, prospects and financial position.

Readers should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere, as of the date made. We do not undertake, and expressly disclaim, any intention to update or alter any statements whether as a result of new information, future events or otherwise except as required by law.

PART I

Item 1. Business.

Unless otherwise indicated in this Annual Report on Form 10-K “we,” “our,” “us,” “the Company,” "Rockwell," “Rockwell Medical,” and other similar terms refer to Rockwell Medical, Inc., together with its consolidated subsidiaries. You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission (“SEC”). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2023 2024 annual meeting of stockholders, our quarterly reports on Form 10-Q and any current reports on Form 8-K that we may file from time to time. You can access free of charge on our website copies of these reports as soon as practicable after they are electronically filed with the SEC. The SEC also maintains a website on the internet that contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC.

Triferic CENTRISOL®, CitraPure®, Dri-Sate®, RenalPure®, RENASOL and ®, SteriLyte®, and Triferic® are registered trademarks of Rockwell. This Annual Report on Form 10-K contains references to our trademarks and trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

BUSINESS OVERVIEW

Rockwell Medical is a healthcare company that develops, manufactures, commercializes, and distributes a portfolio of hemodialysis products for dialysis providers worldwide.

Rockwell is a revenue-generating business business. The Company is the largest supplier of liquid bicarbonate concentrates and the second largest supplier of acid and dry bicarbonate concentrates for dialysis patients in the United States.Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient’s home. This represents a large market opportunity for which we believe Rockwell's products are well-positioned to meet the needs of patients.

Rockwell manufactures hemodialysis concentrates under Current current Good Manufacturing Practices ("cGMP") regulations at its three facilities in Michigan, Texas, and South Carolina totaling approximately 175,000 square feet, and manufactures dry acid concentrate mixers at its facility in Iowa. Additionally, in July 2023, the Company purchased customer relationships, equipment and inventory from Evoqua Water Technologies related to manufacturing and sale of hemodialysis concentrates products, all of which are manufactured under a cGMP contract manufacturing agreement with a third-party organization in Minnesota.

Rockwell delivers the majority of its hemodialysis concentrates products and mixers to dialysis clinics throughout the United States and internationally utilizing its own delivery trucks and third-party carriers. Rockwell has developed a core expertise in manufacturing and delivering hemodialysis concentrates, and has built a longstanding reputation for reliability, quality, and excellent customer service.

In addition to its primary focus on hemodialysis concentrates, Rockwell also has a proprietary parenteral iron product, Triferic® (ferric pyrophosphate citrate ("FPC")), which is indicated to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. While Rockwell has discontinued commercialization of Triferic in the United States, the Company has established several international partnerships with companies seeking to develop and commercialize Triferic outside the United States and is working closely with these international partners to develop and commercialize Triferic in their respective regions. Additionally, Rockwell continues to evaluate the viability of its FPC platform and FPC's potential to treat iron deficiency, iron deficiency anemia, and in different therapeutic settings.

Rockwell was incorporated in the state of Michigan in 1996 and re-domiciled to the state of Delaware in 2019. Our headquarters is located at 30142 Wixom Road, Wixom, Michigan 48393. Our telephone number is (248) 960-9009 and our website is https://www.rockwellmed.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference. reference, and content from or that can be accessed through our website is not part of, or incorporated by reference into, this Annual Report on Form 10-K.

SIGNIFICANT 2022 2023 HIGHLIGHTS

Rockwell Medical's key developments from 2022 2023 include:

- In January 2022, February 2023, we announced regulatory approval of Triferic (dialysate) and Triferic AVNU signed a three-year, multi-million-dollar supply agreement with the largest non-profit dialysis provider in South Korea.
- In April 2022, we expanded our partnership with DaVita, Inc. ("DaVita") through an amended supply agreement. the United States.
- In April 2022, February 2023, we entered into signed a stock three-year, multi-million-dollar product purchase agreement with DaVita and closed the initial $7.5 million tranche. Concerto Renal Services.
- In April 2022, February 2023, we announced that our partner in China, Wanbang Biopharmaceuticals, were named a subsidiary of Shanghai Fosun Pharmaceutical, completed enrollment with over 400 patients for its pivotal phase 3 clinical trial of Triferic in China. 'Great Place to Work'.
- In May 2022, 2023, we announced a 1-for-11 reverse stock split, which became effective at 12:01 a.m. Eastern Time on May 13, 2022. The new CUSIP number following expanded our geographic footprint to sell our hemodialysis concentrates products into the reverse stock split is 774374300.
- In May 2022, we regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. United Arab Emirates.
- In June 2022, 2023, we closed a $15 million financing with Armistice Master Fund Ltd., which consisted of a $12 million registered direct offering, and a $3 million private placement, both priced at-market. were added to the Russell Microcap® Index.
- In June 2022, 2023, we closed the second $7.5 million tranche of the DaVita stock purchase agreement. entered into a three-year co-promotion services agreement with B. Braun Medical Inc.
- In July 2022, Jeil Pharmaceutical commercially launched Triferic in South Korea. 2023, we acquired the hemodialysis concentrates business from Evoqua Water Technologies.
- In July 2022, Mark Strobeck, Ph.D. joined Rockwell as President September 2023, we entered into an amended and Chief Executive Officer and as a member of the Company's Board of Directors. restated products purchase agreement with DaVita, Inc. ("DaVita").
- In August 2022, Heather Hunter September 2023, we entered into a three-year product purchase agreement with Sanderling Renal Services and expanded our distribution capabilities westward into Utah.
- In October 2023, we entered into a three-year product purchase agreement with Centers for Dialysis Care.
- In October 2023, Joan Lau, Ph.D. was appointed to the Company's board of directors.
- In October 2023, Jesse Neri joined the Company as SVP, Chief Corporate Affairs Officer.
- In November 2022, we announced that we reacquired our distribution rights for our hemodialysis concentrates business from Baxter Healthcare Corporation, a subsidiary of Baxter International, Inc. ("Baxter").
- In November 2022, we announced that we discontinued our New Drug Applications ("NDAs") for Triferic and Triferic AVNU in the United States.
- In November 2022, we announced a new business strategy focusing on growing our revenue-generating businesses, which include hemodialysis concentrates and international partnerships for Triferic.
- In November 2022, we announced that we put development work associated with FPC for home infusion on hold. Preliminary results from the microbiology and short-term stability study indicated that the program would likely not meet the FDA's requirements to support the Investigational New Drug ("IND") application and would require significant capital expenditure and resources to conduct additional re-formulation work and a Phase 2 study.
- In November 2022, we announced that we will determine the path forward for FPC in acute heart failure as the Company works towards profitability.
- In November 2022, we announced that we undertook workforce reductions as part of our business restructuring.
- In December 2022, we expanded our hemodialysis concentrates distribution capabilities westward into Minnesota with DaVita. Finance.

OUR STRATEGY

Rockwell Medical is focused on innovative, long-term growth strategies that enhance its products, its processes, and its people, enabling the Company to deliver exceptional value to the healthcare system and provide a positive impact on the lives of hemodialysis patients.

Rockwell's strategy Rockwell is focused on growing the Company's revenue-generating business, which currently includes its portfolio of hemodialysis concentrates and international partnerships for Triferic, pausing further investment in capital-intensive pharmaceutical development programs,and achieving profitability to put the Company in a stronger and more stable financial position.

products. Once the Company achieves sustainable profitability and sustains cash flow from its revenue-generating businesses, business, it will then plans to consider investments in higher-value, longer-term products to develop a broader kidney care products portfolio.

HEMODIALYSIS CONCENTRATES

Rockwell's mission is to provide dialysis clinics and the patients they serve with the highest quality products supported by the best customer service in the industry.

Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient's home. Our hemodialysis concentrates products are used to sustain a patient's life by removing toxins and balancing electrolytes in a dialysis patient's bloodstream.

Rockwell's products are vital to vulnerable patients with end-stage kidney disease. We are an established leader in manufacturing and delivering high-quality hemodialysis concentrates and dialysates, along with certain ancillary products, to dialysis providers and distributors in the United States and abroad. All of our concentrate products are manufactured according to Association for the Advancement of Medical Instrumentation ("AAMI") guidelines and the FDA's Current Good Manufacturing Practice ("cGMP"). cGMP regulations. Our concentrate products are diluted with purified water on-site at the clinic in the dialysis machine, creating dialysate, which works to clean the patient's blood.

A key element of our dialysis business strategy going forward is to improve the strength of our concentrates business. We believe we can achieve this by growing our business through the addition of new customers, expanding our territory coverage, increasing the efficiency by which Rockwell produces its products, and pricing our products appropriately to drive profitability.

Our Products:

Most hemodialysis patients receive dialysis treatment three times per week, or approximately 156 times per year. Most patients who have their dialysis treatment performed at a free-standing clinic have significant and irreversible loss of kidney function. These are commonly referred to as "chronic" dialysis patients. Patients who undergo dialysis in hospitals for temporary loss of kidney function are typically referred to as "acute" dialysis patients. The small percentage of chronic dialysis patients who receives receive their treatment at home are referred to as "home" dialysis patients. In each setting, a dialysis machine dilutes concentrated solution, such as Rockwell's concentrate products, with purified water. The resulting solution is called dialysate. Dialysate is pumped through an artificial kidney or filter (called a dialyzer) while the patient's blood is pumped through a semi-permeable membrane inside the dialyzer in the opposite direction the dialysate is flowing. The dialysate can exchange bicarbonate, sodium, calcium, magnesium and potassium into the patient's blood, while removing fluid and waste. Dialysate generally contains dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate, and citric acid or acetic acid. The patient's physician chooses the proper concentrations required for each patient based on each particular such patient's needs.

In addition to using concentrate products during every in-center treatment, a dialysis provider also uses other products such as blood tubing, fistula needles, dialyzers, drugs, specialized component kits, dressings, cleaning agents, filtration salts, and other supplies, some of which we sell.

CitraPure Citric Acid Concentrate

Our CitraPure Concentrate is citric acid-based and 100% acetate-free, in contrast to the acetate-based products used for many years. CitraPure has been shown to not promote inflammation associated with acetate-based products and the reduction in inflammation is beneficial to improving patient outcomes. Citrate acts as an anticoagulant and has been shown in clinical studies to reduce the need for heparin during dialysis treatment (CitraPure is not indicated for heparin sparing). acetate-free. CitraPure is packaged as a liquid acid concentrate in 55 gallon 55-gallon drums and one-gallon jugs sold in cases of four, and as a dry powder acid concentrate for use with our Dry Acid Concentrate Mixer in 25 gallon 25-gallon cases.

Dri-Sate Dry Acid Concentrate

Our Dri-Sate Concentrate is our an acetic acid-based product. Dri-Sate is packaged as a dry powder acid concentrate for use with our Dry Acid Concentrate Mixer in 25 gallon 25-gallon cases.

RenalPure Liquid Acid Concentrate

Our RenalPure Liquid Concentrate is our an acetic acid-based product and is packaged in 55 gallon 55-gallon drums and in one-gallon jugs (sold in cases of four).

RenalPure Bicarbonate Concentrate

RenalPure bicarbonate is a dry powder mixed on-site at the clinic and is packaged in bulk and individual treatment sizes.

SteriLyte Bicarbonate Concentrate

SteriLyte bicarbonate is a liquid packaged in cases of four one gallon jugs. one-gallon jugs (sold in cases of four) and is used mainly in acute care settings.

CENTRISOL and RENALSOL Hemodialysis Concentrates

Our CENTRISOL hemodialysis concentrates consist of acid and bicarbonate formulations suitable for 45X dilution three-stream hemodialysis devices.Our RENASOL acid and bicarbonate concentrates are compatible with 36X dilution devices. CENTRISOL and RENASOL liquid acids are packaged in 55-gallon drums or in one-gallon jugs (sold in cases of four). CENTRISOL and RENASOL bicarbonate concentrates are packaged as liquid in one-gallon jugs (sold in cases of four) or as dry powder in bulk and individual treatment sizes.

Dry Acid Concentrate Mixer

Our Dry Acid Concentrate Mixer is designed for our CitraPure and Dri-Sate Dry Acid products and enables the clinic to mix acid concentrate on-site. Clinics using our Dry Acid Concentrate products realize numerous advantages, including lower cost per treatment, reduced storage space requirements, reduced number of deliveries and more flexibility in scheduling deliveries, while enabling us to reduce distribution and warehousing costs.

RenalPure and SteriLyte Bicarbonate Concentrate

RenalPure bicarbonate is a dry powder mixed on-site at the clinic and is packaged for bulk and individual treatment and SteriLyte bicarbonate is a liquid packaged in cases of four one-gallon jugs and is used mainly in acute care settings.

Ancillary Products

We offer certain ancillary products to selected customers including testing supplies, 5% acetic acid cleaning agents, 6% bleach for disinfection, solution, 5% and 2% citric acid descale, descaler, filtration salts, and other supplies items used by hemodialysis providers.

Market Opportunity:

Rockwell's vision is to become the leading global supplier of all hemodialysis concentrates.

Today, Rockwell is the leading supplier of liquid bicarbonate concentrates and the second largest supplier of acid and dry bicarbonate concentrates for dialysis patients in the United States. According to an independent research report that Rockwell commissioned from L.E.K. Consulting LLC in 2022, the hemodialysis concentrates market in the United States alone is currently valued at $380 million and is anticipated to grow to approximately $500 million by 2026. 2026, up from $380 million in 2022. This is driven primarily by an increasing number of patients suffering from end-stage kidney disease. Hemodialysis concentrates represents represent a large market opportunity for which we believe Rockwell's products are well-positioned to meet the needs of patients. Rockwell is one of only two suppliers that has the manufacturing scalability and transportation infrastructure to service the over 7,200 more than 12,000 individual purchasing facilities (including outpatient dialysis clinics and hospitals) in the United States along with select international markets.

Sales and Marketing:

Prior to the second quarter of 2022, Rockwell's concentrates business operated at a loss. This loss was accelerated due to inflation, which has increased our manufacturing and operating costs. We undertook discussions with our largest customers to renegotiate our existing supply contracts to improve the profitability of this business line. On April 6, 2022, we amended our agreement with our long-time partner, DaVita, a leading provider of kidney care, to enable us to stabilize our concentrates business. The amended agreement provides for changes to pricing, cost share, cost cutting, and joint efforts to improve supply chain. In addition to the amended agreement, DaVita invested $15 million in preferred stock in two equal tranches. The first tranche of $7.5 million was funded on April 7, 2022. The second tranche of $7.5 million was funded on June 16, 2022. We continue to review our entire supply chain to identify opportunities for improvement, prioritizing initiatives that will have the largest impact on long-term efficiency, profitability, and growth.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter Healthcare Corporation ("Baxter") and agreed to terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminated December 31, 2022. Rockwell agreed to provide certain services to a group of Baxter customers until March 31, 2023. Under the exclusive distribution agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products in the United States and certain other countries. Rockwell manufactured all hemodialysis concentrates products and provided customer service and order delivery to nearly all U.S. customers. Following the reacquisition of these rights, Rockwell is now able to sell its hemodialysis concentrates products directly to dialysis clinics throughout the United States and around the world. Additionally, Rockwell is now able to independently price its products, eliminate costs associated with manufacturing covenants, improve manufacturing efficiencies and realize the full benefits from those improvements, and develop, in-license, or acquire new products to develop a broader kidney care products portfolio. This is expected to improve Rockwell's overall profitability and set the Company on a positive growth trajectory.

On June 29, 2023, the Company announced that it entered into a three-year co-promotion services agreement with B. Braun Medical Inc. ("B. Braun"), a leader in renal therapies including innovative, high-quality products for hemodialysis. As part of the agreement, Rockwell designates B. Braun as an independent, non-exclusive representative to promote the Company's hemodialysis concentrates products to dialysis providers in the United States with a focus on the west coast. All terms of the sale of any Rockwell product, including price, delivery schedule, and terms and conditions, are set by Rockwell at the Company's sole discretion. All orders are directed to, and processed by, Rockwell. B. Braun receives a fee for any sales generated by its promotional efforts.

On July 10, 2023, the Company executed and consummated the transactions contemplated by an Asset Purchase Agreement (the “Purchase Agreement”) with Evoqua Water Technologies LLC ("Evoqua") (the "Evoqua Acquisition"). Subject to the terms and conditions of the Purchase Agreement, at the closing of the transaction (the “Closing”), the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to manufacturing and selling of hemodialysis concentrates products, all of which are manufactured under a contract manufacturing agreement with a third-party organization.

On September 18, 2023, Rockwell and our long-time partner, DaVita, a leading provider of kidney care, entered into an Amended and Restated Products Purchase Agreement (the "Amended Agreement"), which amends and restates the Product Purchase Agreement, dated July 1, 2019, as amended, under which the Company supplies DaVita

with certain dialysis concentrates. Under the Amended Agreement, the Company and DaVita agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment to Rockwell on or after December 1, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, to further extend the term through December 31, 2025. In the event of such an extension, product pricing will be increased for the extended term. In addition, DaVita is required to provide the Company with nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for the amount forecasted, purchase additional product, or the Company may terminate the Amended Agreement. Upon expiration or termination of the Amended Agreement, and upon request by DaVita, the Company has agreed to provide transition services to DaVita during a transition period.

In 2023, Rockwell entered into several long-term product purchase agreements, which include supply and purchasing commitments from certain parties. These agreements include the largest non-profit dialysis provider in the United States; Concerto Renal Services, the largest provider of dialysis in skilled nursing facilities in the United States; Sanderling Renal Services, Inc., a full-service provider of in-center, home dialysis and renal telemedicine services focusing on patients in rural and underserved communities across the United States; Centers for Dialysis Care, the largest non-profit, independent outpatient

dialysis provider in Northeast Ohio; Houston Methodist, a leading health system and academic medical center; Dialyze Direct, a leading provider of home dialysis services in the skilled nursing facility setting; and Outset Medical (Nasdaq:OM), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis with its Tablo® Hemodialysis System, which is FDA-cleared for use from the hospital to the home.

We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Nipro Medical Corporation is the primary distributor of our dialysis concentrates in certain countries in Latin America that were not covered under the Distribution Agreement.

Dialysate concentrates accounted for approximately 98.4% 97.2% of our revenue for the year ended December 31, 2022. Approximately 91.1% December 31, 2023, of our sales for the year ended December 31, 2022 were which approximately 91.5% was to distributors and customers for use in the United States.

Customers:

We currently operate in one market segment, the hemodialysis market, which involves the manufacture, sale and distribution of hemodialysis products to hemodialysis clinics, including pharmaceutical, dialysis concentrates, dialysis kits and other ancillary products used in the dialysis process.

DaVita, accounted for 47% of our concentrate sales in 2023 and 46% of our concentrate sales in 2022 and 47% of our concentrate sales in 2021. 2022. Our accounts receivable from this customer were $1.9 million $2.1 million and $1.0 million $1.9 million as of December 31, 2022 December 31, 2023 and 2021, 2022, respectively. In August July 2019, we entered into the Products Purchase Agreement with DaVita, with an initial term expiring on December 31, 2023. On April 6, 2022, we entered into an amendment to the Products Purchase Agreement under which we agreed to a price increase, effective May 1, 2022, as well as the pass-through of certain costs, determined on a quarterly basis. Certain costs are subject to a cap. Also on April 6, 2022, the Company and DaVita entered into a Securities Purchase Agreement (the “SPA”), which provided for the issuance by the Company of up to $15 million of preferred stock to DaVita (see "Preferred Stock" section in Note 12 below).

In October 2014, On September 18, 2023, we entered into the Distribution Amended Agreement with Baxter, DaVita under which was amended in June 2017 and March 2020, pursuant to which Baxter received exclusive distribution rights the Company supplies DaVita with certain dialysis concentrates. See "Material Agreements" below for our concentrate products in more information on the United States, a commitment by Rockwell to maintain a specified manufacturing capacity for Baxter, a cap upon the net amount of reimbursable transportation expenses and modified extension terms. Our domestic customer contracts for the supply of dialysis concentrate products that permitted assignment to Baxter without consent were assigned to Baxter. As a result, for 2022 and 2021, our direct sales to Baxter aggregated approximately 29% and 26% of sales, respectively, and we had accounts receivable from Baxter of $2.3 million and $3.5 million as of December 31, 2022 and 2021, respectively. As noted above, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Amended Agreement.

No other customers accounted for more than 10% of our sales in any of the last three years. Nipro Medical Corporation, accounted for 7% and 8% of our sales in 2022 and 2021, respectively.

DaVita the former Baxter customers, and Nipro Medical Corporation are important to our business, financial condition and results of operations. The loss of any significant accounts could have a material adverse effect on our business, financial condition and results of operations.

See Item 1A “Risk Factors” for a discussion of certain risks related to our key customers.

The majority of our international sales in each of the last two years were sales to domestic distributors that were resold to end users outside the United States. Our total international sales, including sales made through domestic distributors for resale outside the United States, aggregated 9% and 10% 9% of our overall sales in 2022 2023 and 2021, 2022, respectively.

See Item 1A “Risk Factors” for a discussion of certain risks related to our foreign sales.

Competition:

In the United States, our principal competitor for concentrate products is Fresenius Medical Care NA (“Fresenius”), a vertically integrated manufacturer and marketer of dialysis devices, drugs and supplies and operator of dialysis clinics, which has substantially greater financial, technical, manufacturing, marketing, and research and development

resources than we do. Fresenius, through its Fresenius Kidney Care division, operates approximately 2,600 clinics and treats approximately 37% of the in-center hemodialysis patients in the United States. Fresenius also manufactures and sells a full range of renal products, including dialysis machines, dialyzers, concentrates, and other supplies used in hemodialysis. Fresenius services clinics owned by others with its products where it commands a market leading position in its key product lines. Fresenius manufactures its concentrate concentrates in its own regional manufacturing facilities. Fresenius and Rockwell are the two major dialysis concentrate suppliers in the United States.

Quality Assurance and Control:

We have established a Quality Management System ("QMS"), which defines systems and procedures used to assure quality in the design, manufacture, and delivery of our finished device and pharmaceutical products.

We operate under FDA guidelines regulations and place significant emphasis on providing quality products and services to our customers. We have established an organizational structure and quality system procedures to ensure our device products are designed and produced to meet product quality requirements and FDA guidelines. The Grapevine, Texas facility is certified to

ISO 13485:2016. Dialysis products are manufactured and tested using validated equipment and defined process controls to ensure rigorous conformance to specifications. To assure quality and consistency of our dialysis concentrates, analytical testing is performed using validated instrument methods to verify that the chemical properties and microbial limits of each product lot comply with the specifications required by industry standards. Our concentrates are labeled per FDA FDA's Labeling and Packaging Control Requirements, including a Unique Device Identifier ("UDI") code, requirements to ensure traceability of distributed products. Our quality program activities also include qualification and ongoing assessments of suppliers of raw materials, packaging components and finished goods, and quality management reviews designed to inform management of key issues that may affect the quality of products, assess the effectiveness of our quality systems, and identify areas for improvement.

The raw materials and packaging materials for our hemodialysis concentrates, the components for our hemodialysis kits and the ancillary hemodialysis products we distribute are generally available from several potential suppliers. The raw materials for our concentrate products consist primarily of chemical ingredients which meet or exceed the requirements of United States Pharmacopeia (“USP”). Key raw materials used in our hemodialysis concentrates include USP grade sodium chloride, calcium chloride, magnesium chloride, potassium chloride, dextrose, citric acid, glacial acetic acid, and sodium bicarbonate. Key packaging components include drums, bottles, caps, film/bags, boxes, and labels. We generally negotiate pricing and approximate material quantities for our chemicals on an annual basis and utilize blanket purchase orders with monthly release schedules to meet our needs for production.

See Item 1A “Risk Factors” for a discussion of certain risks related to our key suppliers.

Distribution and Delivery Operations:

The majority of our domestic dialysis concentrate products are delivered through our subsidiary, Rockwell Transportation, Inc., which operates a fleet of trucks used to deliver products to our customers. Rockwell distribution and delivery operated under the Distribution Agreement on behalf of Baxter for domestic business. On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and agreed to terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminated December 31, 2022. Rockwell agreed to provide certain services to a subgroup of Baxter's customers until March 31, 2023.

Triferic®

Our first two branded products from our FPC platform, Triferic® (dialysate) and Triferic® AVNU are indicated to maintain hemoglobin in patients undergoing hemodialysis. We began commercializing Triferic and Triferic AVNU in the United States in the second half of 2019 and in early 2021, respectively. In addition, Rockwell established six international partnerships to develop and commercialize Triferic in China, India, Korea, Turkey, Peru and Chile.

In 2022, Rockwell undertook a strategic review of Triferic's viability in the United States. Triferic was launched into a very competitive marketplace with well-entrenched products and a lack of consensus regarding unmet medical needs for dialysis patients with anemia. Due to its limited market adoption, unfavorable reimbursement, and absence of interest from other companies to license or acquire Triferic despite Rockwell's significant effort to partner the program, the Company discontinued its NDAs New Drug Applications ("NDAs") for Triferic and Triferic AVNU in the United States in the fourth quarter of 2022. Sustaining Triferic commercially in the United States resulted in a losses to Rockwell annually. The decision to discontinue the NDAs was not made lightly as the Company realizes the direct impact this action had on patients using the products. Triferic and its approved presentations were not discontinued for safety reasons.

International Partnerships:

Rockwell continues to support its partners outside the United States who that have exclusive license agreements to develop and commercialize Triferic in China, India, Korea, Turkey, Peru and Chile. Partnering in these regions allows us to better leverage the development, regulatory, commercial presence, and expertise of business partners to increase sales of our products throughout the world. We believe there is still potential opportunity for Triferic internationally and will work diligently to support our partners, which requires minimal financial commitment from Rockwell and provides us with potential for near- and long-term revenue. We continue to pursue international licensing opportunities in other countries and regions.

Quality Assurance and Control

We have established a Quality Management System ("QMS") which defines systems and procedures used to assure quality in the design, manufacture, and delivery of our finished device and pharmaceutical products.

We utilize Contract Manufacturing Organizations (“CMOs”) to manufacture and package our drug products for sale. These contract manufacturers are FDA registered drug manufacturing establishments. We follow defined procedures to qualify manufacturers of our products and to review and approve all manufactured products to ensure compliance with FDA cGMP regulations. We ensure our CMOs have established robust quality systems and employ validated processes to ensure the quality and compliance of our drug products to their specifications prior to distribution.

We have engaged CMOs for the manufacture and packaging of Triferic. We have one supplier for the active pharmaceutical ingredient (“API”) utilized in Triferic and one fill and finish vendor for the liquid formulation of Triferic (dialysate) and Triferic AVNU. New production is generally initiated via purchase orders, though we will evaluate the need for supply agreements based on our forecasted product needs. The lead time to qualify and obtain regulatory approval for an additional CMO could be lengthy. Any material dispute, lack of quality of the product, or loss of any significant drug product supplier could have a material adverse effect on our business, financial condition and results of operations.

See Item 1A “Risk Factors” for a discussion of certain risks related to our key suppliers.

RESEARCH AND DEVELOPMENT PIPELINE

FPC for home infusion is Rockwell's follow-up to Triferic and utilizes the FPC platform in the home infusion setting.

In late 2021, Rockwell filed an IND application with the FDA for the treatment of iron deficiency anemia in patients, who are receiving medications in the home infusion setting. During the second quarter 2022, Rockwell provided the FDA with supplemental data to be used in Rockwell's clinical studies and to clinically support the Company's IND application for home infusion. The FDA placed this program on Clinical Hold and requested that additional data related to the microbiology and short-term stability of this formulation be provided to support the application. During the third quarter of 2022, Rockwell conducted a microbial challenge and short-term stability study of FPC for Home Infusion, in accordance with FDA guidance, to support the Company’s IND application. Preliminary results from the microbiology and short-term stability study indicated that the program would likely not meet the FDA's requirements to support the IND application and would require significant capital expenditure and resources to support additional re-formulation work and conduct a Phase 2 study. As a result, Rockwell has put development work associated with FPC for Home Infusion on hold.

Rockwell is also exploring FPC’s impact on the treatment of hospitalized acute heart failure patients, which affects more than one million people in the United States annually. Rockwell conducted a pre-IND meeting with the FDA in 2022 and will determine the path forward for FPC in acute heart failure as the Company works toward profitability.

MATERIAL AGREEMENTS

Distribution Agreement with Baxter

Pursuant to the Exclusive Distribution Agreement dated October 2, 2014 (as amended, the “Distribution Agreement”), Baxter was our exclusive agent for commercializing our hemodialysis concentrate and ancillary products in the United States to clinics other than DaVita and various foreign countries for an initial term of 10 years ending October 2, 2024. We retained sales, marketing and distribution rights for our hemodialysis concentrate products for our international customers and in those countries in which we had an established commercial presence. In the fourth quarter of 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. Rockwell is was required to pay Baxter a fee for the reacquisition of its distribution rights. This fee is payable was paid in two equal installments on January 1, 2023 and April 1, 2023.

Following the reacquisition of the distribution rights, Rockwell is now able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world. Baxter and Rockwell are working closely together to transition customers’ purchases of Rockwell’s hemodialysis concentrates from Baxter to Rockwell.

Products Purchase Agreement with DaVita

In August 2019, we signed On September 18, 2023, Rockwell and our long-time partner, DaVita, a Products Purchase Agreement (the "Products Purchase Agreement") with DaVita. Pursuant to leading provider of kidney care, entered into the Products Purchase Amended Agreement. Under the Amended Agreement, the Company supplies certain and DaVita dialysis centers with dialysis acid concentrate (i.e. agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment of $0.4 million to Rockwell on or after December 1, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, CitraPure (Liquid and Dry Acid), Dri-Sate Dry Acid or RenalPure Liquid Acid) and bicarbonate (i.e., RenalPure® Bicarbonate Powder or SteriLyte Liquid Bicarbonate) to further extend the term through December 31, 2023 (the “Initial Term”), subject to certain terms and conditions. The Products Purchase Agreement is a fixed price contract that allows December 31, 2025. In the event of such an extension, product pricing will be increased for prices increases only under certain conditions and only after following procedures set forth in the Products Purchase Agreement.extended term. In addition, the

Products Purchase Agreement requires us DaVita is required to maintain twenty-one days of inventory provide the Company with nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for DaVita and contains penalties if we fail to supply DaVita.If, upon the amount forecasted, purchase additional product, or the Company may terminate the Amended Agreement. Upon expiration or termination of the Initial Term, Amended Agreement, and upon request by DaVita, the parties have not completed an extension or a new purchase agreement, the Purchase Agreement will continue in effect until terminated by either party with 90 days written notice or until the completion of an extension or new purchase agreement.On April 6, 2022, we entered into an

amendment to the Products Purchase Agreement under which we Company has agreed to provide transition services to DaVita during a price increase, effective May 1, 2022, as well as the pass-through of certain costs, determined on a quarterly basis. Certain costs are subject to a cap.transition period.

Product License Agreements

We are party to a Licensing Agreement between the Company and Charak, LLC ("Charak") dated January 7, 2002 (the "2002 Agreement") that grants the Company exclusive worldwide rights to certain patents and information related to our Triferic products. On October 7, 2018, we entered into a Master Services and IP Agreement (the "Charak MSA") with Charak and Dr. Ajay Gupta, who is the former Executive Vice President and Chief Scientific Officer of the Company. Pursuant to the Charak MSA, the parties entered into three additional agreements described below related to the license of certain soluble ferric pyrophosphate ("SFP") intellectual property owned by Charak, as well as the Employment Agreement (defined below). The Charak MSA provided for a payment of $1,000,000 to Dr. Gupta, payable in four quarterly installments of $250,000 each on October 15, 2018, January 15, 2019, April 15, 2019 and July 15, 2019, and reimbursement for certain legal fees incurred in connection with the Charak MSA. As of December 31, 2019, all payments under the Charak MSA were paid.

Pursuant to the Charak MSA, the aforementioned parties entered into an Amendment, dated as of October 7, 2018 (the "Charak Amendment"), to the 2002 Agreement, under which Charak granted the Company an exclusive, worldwide, non-transferable license to commercialize SFP for the treatment of patients with renal failure. The Charak Amendment amends the royalty payments due to Charak under the 2002 Agreement such that the Company is liable to pay Charak royalties on net sales by the Company of products developed under the license, which includes the Company's Triferic product, at a specified rate until December 31, 2021 and thereafter at a reduced rate from January 1, 2022 until February 1, 2034. In addition, the Company is required to pay Charak a percentage of any sublicense income during the term of the agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid patent claim, on a country-by-country basis, and not be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid patent claim, on a country-by-country basis.

Also pursuant to the Charak MSA, the Company and Charak entered into a Commercialization and Technology License Agreement Triferic IV, dated as of October 7, 2018 (the "IV Agreement"), under which Charak granted the Company an exclusive, sublicensable, royalty-bearing license to SFP for the purpose of commercializing certain intravenous-delivered products incorporating SFP for the treatment of iron disorders worldwide for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. The Company is liable to pay Charak royalties on net sales by the Company of products developed under the license at a specified rate until December 31, 2021. From January 1, 2022 until February 1, 2034, the Company is liable to pay Charak a base royalty at a reduced rate on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the IV Agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and no be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

Also pursuant to the Charak MSA, the Company and Charak entered into a Technology License Agreement TPN Triferic, dated as of October 7, 2018 (the "TPN Agreement"), pursuant to which Charak granted the Company an exclusive, sublicensable, royalty-bearing license to SFP for the purpose of commercializing worldwide certain Total Parenteral Nutrition (TPN) products incorporating SFP. The license grant under the TPN Agreement continues for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. During the term of the TPN Agreement, the Company is liable to pay Charak a base royalty on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the TPN Agreement, which amount shall not be less than a minimum royalty on net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and not be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

GOVERNMENT REGULATION

We are regulated by the FDA under the Federal Food, Drug and Cosmetic Act (the "FD&C Act"), as well as by other federal, state and local agencies. We hold several FDA product approvals including for both drugs and medical devices.

The testing, manufacture and sale of our hemodialysis concentrates and the ancillary products we distribute are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign agencies. Under the FD&C Act, and FDA regulations, the FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and marketing of medical devices and drugs. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution.

We have developed and are developing drug candidates utilizing the FPC Platform. The development and regulatory approval process for new drugs and additional indications for approved drugs includes preclinical testing and human clinical trials and is lengthy and uncertain. Before marketing any pharmaceutical or therapeutic product in the United States, the product must undergo rigorous preclinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FD&C Act.

Moreover, the FDA imposes substantial requirements on new product research and the clinical development, manufacture and marketing of pharmaceutical products, including testing and clinical trials to establish the safety and effectiveness of these products.

Medical Device Approval and Regulation

A Pursuant to its authority under the FD&C Act, the FDA has jurisdiction over medical devices. The FDA regulates, among other things, the research, design, development, preclinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Unless an exemption applies, each new or significantly modified medical device may be

marketed in the United States only with prior authorization from requires either a premarket notification to the FDA unless it is subject requesting permission for commercial distribution under Section 510(k) of the FD&C Act, also referred to as a specific exemption. 510(k) clearance, or FDA approval of a premarket approval application ("PMA").

Device Classification

Under the FD&C Act, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I devices (general controls) and some Class II devices (general and special controls) products are exempt from the premarket notification (i.e., requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents, and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) clearance) requirements. premarket notification process.

Class III devices generally require "premarket approval" ("PMA") from include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described in further detail below. FDA grants above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction.

510(k) Pathway

To obtain 510(k) clearance, when a premarket notification must be submitted under Section 510(k) of the submitted information establishes FD&C Act demonstrating that a the proposed device is "substantially equivalent" in terms of safety and effectiveness "substantially equivalent" to a legally predicate device. A predicate device is a legally-

marketed device that is not subject to premarket approval. A legally marketed device is approval, i.e., a "pre-amendment" device that was legally marketed prior to May 28, 1976 (for (pre-amendments device) and for which a PMA is not required), required, a device that has been reclassified from Class III to Class I II or II, I, or a device which has been that was found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, but it can take considerably longer, depending on the extent of FDA's requests for additional information and the amount of time a sponsor takes to fulfill them. After a 510(k) is submitted, the FDA in recent years has been requiring determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) submission. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) premarket notification within 90 days of receiving the 510(k) submission. As a practical matter, clearance often takes longer, and clearance is never assured.

Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous demonstration premarketing requirements of substantial equivalence than in the past, including requiring clinical trial data in some cases. For any devices that are cleared PMA process, or seek reclassification of the device through the *de novo* process.

After a device receives 510(k) process, modifications clearance, any modification, including modification to or enhancements deviation from design, manufacturing processes, materials, packaging and sterilization that could significantly affect its safety or effectiveness, or that would constitute a new or major change in the its intended use, may require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA requires a new 510(k) clearance or approval of a PMA application for any modifications to a previously-cleared product, the applicant may be required to cease marketing or recall the modified device until clearance or approval is received. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite 510(k) or PMA application(s).

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure.

The *de novo* classification procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (the "FDASIA"), a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. The FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under the FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application, though in practice

the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for Special Controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that General Controls would be inadequate to control the risks and Special Controls cannot be developed.

PMA Pathway

A PMA must be submitted if a device cannot be cleared through the 510(k) clearance or *de novo* process. A PMA must be supported by extensive data, including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data, and labeling, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

Following receipt of a PMA, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory panel may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory panel, but it considers such recommendations carefully when making decisions. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical trial data and clinical trial sites, and a QSR inspection of the manufacturing facility and processes. The FDA can delay, limit, or deny approval of a PMA for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require new 510(k) submissions. It additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter or an approvable letter. The latter usually takes three contains a number of conditions that must be met in order to six secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data are submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain, and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMAs or PMA supplements may be required for modifications to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, components, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA, except that the supplement is limited to information needed to support any changes from the date of submission to obtain 510(k) clearance, device covered by the approved PMA and may take substantially longer. Our hemodialysis concentrates (acid or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA, as a condition of approval, the FDA may also require some form of postmarket studies or postmarket surveillance, whereby the applicant follows certain patient groups for a number of years and bicarbonate) and other ancillary products are categorized as Class II devices.

Class III devices typically are devices that sustain or support life, prevent impairment makes periodic reports to the FDA on the clinical status of human those patients when necessary to protect the public health or present a potential unreasonable risk of illness to provide additional or injury. A Class III device generally must receive approval through longer term safety and effectiveness data for the device. The FDA may require postmarket surveillance for certain devices approved under a PMA application, or cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility, devices where the failure of which requires proving would be reasonably likely to have serious adverse health consequences, or devices expected to have significant use in pediatric populations. The FDA may also approve a PMA with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution, and use.

Clinical Trials

Clinical trials are almost always required to the FDA. The process of obtaining support a PMA approval is expensive and uncertain. It usually takes approximately one year to obtain approval after filing the request, and may take substantially longer.

If human clinical trials of a device are sometimes required whether for a 510(k) premarket notification. In the United States, these trials often require submission or a PMA of an application and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or the distributor of the device) will have to file for an investigational device exemption ("IDE" ("IDE") if the investigation involves a significant risk device. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE—without affirmative submission of an IDE application prior to commencing human clinical trials. the FDA—once certain requirements are addressed and institutional review board ("IRB") approval is obtained. The IDE application must be supported by appropriate data, typically including the results of such as animal and laboratory testing. If testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a

specified number of patients, unless the product candidate is deemed a non-significant risk device and is eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and one or more

appropriate Institutional Review Boards ("IRBs"), the device may be shipped for the purpose of conducting the investigations without compliance with all of the requirements of the FD&C Act and human clinical trials may begin. The FDA will specify the number of investigational sites and the number of patients that may be included in the investigation. If the device does not present a "significant risk" to the patient, a sponsor may begin IRBs at the clinical trial after obtaining sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study by one or more appropriate IRBs without sponsors and study investigators. Clinical trials must further comply with the need FDA's Good Clinical Practices ("GCP") requirements for FDA approval.

Any devices manufactured or distributed by us pursuant to FDA clearances or approvals IRB approval and for informed consent and other human subject protections. Required records and reports are subject to continuing regulation inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product candidate.

Postmarket Requirements—U.S.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;
- Restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval or clearance of a 510(k) for certain state agencies. As a manufacturer of medical devices for marketing in the United States, we are required to adhere to regulations, including 21 CFR 820, which is commonly referred to as the Quality System Regulation, setting forth detailed cGMP requirements, which include testing, control and documentation requirements. We must also comply with product modifications;
- medical device reporting regulations, which require that we manufacturers report to the FDA any incident in which our products if their device may have caused or contributed to a death or serious injury or malfunctioned in which our products malfunctioned and, if the malfunction were to recur, it a way that would be likely to cause or contribute to a death or serious injury. Under such injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a scenario, our products risk to health posed by the device or to remedy a violation of the FD&C Act that may be present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Additionally, manufacturers are subject to voluntary recall unannounced inspections by us the FDA to determine compliance with the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or required recall unscheduled inspections by the FDA. Labeling A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and promotional activities the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls. In addition, the FDA can issue warning letters or untitled letters, impose injunctions, suspend regulatory clearance or approvals, ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement or refund of these devices, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also initiate action for civil penalties and/or criminal prosecution of such violations.

There are also certain requirements of state, local, and foreign governments that we must comply with in the manufacturing and marketing of our products. We will need to maintain customer complaint files, record all lot numbers of disposable products, and conduct periodic audits to assure compliance with applicable regulations. We place special emphasis on customer training and advise all customers that device operation should be undertaken only by qualified personnel. In addition to laws and regulations in the United States, we are subject to scrutiny by a variety of laws and regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates.

Postmarket Requirements—EU

The regulatory review process varies from country to country and may in some cases require the FDA and, in certain circumstances, by the Federal Trade Commission. The FD&C Act prohibits the marketing submission of approved medical devices for unapproved uses.

We clinical data. Our international sales are subject to routine inspection by regulatory requirements in the FDA countries in which our product candidates are sold. In addition, the EU has adopted the EU Medical Device Regulation (EU 2017/745) (the "EU MDR") which imposes stricter requirements for the marketing and sale of medical devices than in the United States, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The transition period provided for in the EU MDR for existing CE certifications issued under the previous Medical Devices Directive will end on May 26, 2024. For certain state agencies for compliance medical devices, the transition period was extended, ending between December, 31, 2026 and December 31, 2028, depending on the class of the device and the fulfillment of certain additional conditions. (Regulation (EU) 2023/607). Complying with cGMP these regulations may require us to incur significant expenditures. Failure to meet these regulatory requirements could adversely impact our business in the EU and other applicable quality system regulations. regions that tie their product registrations to the EU requirements.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, transportation and disposal of hazardous or potentially hazardous substances.

Our hemodialysis concentrate products and other ancillary devices are subject the FDA 510(k) requirements.

We have 510(k) clearance from the FDA to market hemodialysis concentrates in both liquid and powder form. In addition, we have received 510(k) clearance for our Dry Acid Concentrate Mixer.

We must comply with the FD&C Act and related laws and regulations, including cGMP, to retain 510(k) clearances. We cannot assure you that we will be able to maintain our 510(k) clearances from the FDA to manufacture and distribute our products. If we fail to maintain our 510(k) clearances, we may be required to cease manufacturing and/or distributing our products, which would have a material adverse effect on our business, financial condition and results of operations. If any of our FDA clearances are denied or rescinded, sales of our products in the United States would be prohibited during the period we do not have such clearances.

Drug Approval and Regulation

The marketing of pharmaceutical products in the United States, such as Triferic, requires the approval of the FDA. The FDA has established regulations, guidelines and safety standards which apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of our new iron maintenance therapy product and other pharmaceutical products. The steps required before a pharmaceutical product can be produced and marketed for human use include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials; (iv) submission to the FDA of an NDA; and (v) review and approval of the NDA by the FDA. An NDA generally is required for products with new active ingredients, indications, routes of administration, dosage forms or strengths. An NDA requires that complete clinical studies of a product's safety and efficacy be submitted to the FDA, the cost of which is substantial. The costs are often less, however, for new delivery systems, which utilize already approved drugs than for drugs with new active ingredients.

Pre-clinical studies are conducted to obtain preliminary information on a pharmaceutical product's efficacy and safety in animal or in vitro models. The results of these studies are submitted to the FDA as part of the IND and are reviewed by the FDA before human clinical trials begin. Human clinical trials may begin 30 days after receipt of the IND by the FDA unless the FDA objects to the commencement of clinical trials.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing the product primarily for safety, metabolism and pharmacologic action in a small number of patients or healthy volunteers at one or more doses. In Phase 2 trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase 1 trials with the primary intent of determining the effective dose range. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at a large number of test sites. A clinical plan, or protocol, accompanied by documentation from the institutions participating in the trials, must be received by the FDA prior to commencement of each of the clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA in a timely manner. The FDA may refuse to file an NDA if it is not sufficiently complete to permit substantive review. The FDA may deny an NDA by way of a complete response letter if applicable regulatory criteria are not satisfied or it may require additional testing, including pre-clinical, clinical and or product manufacturing tests. Even if such data are submitted, the FDA may ultimately deny approval of the product. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in a manufacturing facility, an NDA supplement may be required to be submitted to the FDA. Product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. The FDA may require testing and surveillance programs to monitor the effect of products which have been commercialized and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

Manufacturing facilities are subject to periodic inspections for compliance with regulations, such as cGMP requirements, and each domestic drug manufacturing facility must be registered with the FDA. Foreign regulatory authorities may also have similar regulations. We expend significant time, money and effort in the area of quality assurance to comply with all applicable requirements. FDA approval to manufacture a drug is site specific. In the event an approved manufacturing facility for a particular drug becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations. Manufacturers and distributors must comply with various post-market requirements, including adverse event reporting, re-evaluation of approval decisions and notices of changes in the product or in the process or procedures used to manufacture a product.

Once an NDA is approved, a product is subject to certain post-approval requirements. NDA applicants are required to submit to FDA information about any adverse event associated with the use of an approved drug, whether or not the adverse event is considered drug related. If a marketed drug is found to be potentially harmful or does not comply with applicable requirements, the manufacturer may recall the product. The FDA regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Major changes and some moderate changes to an approved drug, or to the conditions established in the approved NDA, may require the submission and approval of a new NDA or NDA supplement before the change can be implemented. Other changes may be made at the time of FDA's receipt of the NDA supplement or may be described in our next annual report for the approved NDA.

Pediatric Requirements

Under the Pediatric Research Equity Act ("PREA"), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may

grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication where orphan designation has been granted.

The Best Pharmaceuticals for Children Act ("BPCA") provides NDA holders a six-month extension of the marketing exclusivity or patent protection for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the applicant agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Other Government Regulations

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical and medical device industry or on our business or operating results. Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, laboratory practices, and environmental protection and may be subject to other present and possible future local, state, federal and foreign regulations. We do not expect that compliance with these regulations, including environmental laws, will have a material adverse impact on our financial condition.

In August 2022, Congress passed the Inflation Reduction Act ("IRA"), which for authorizes the first time authorizes U.S. Department of Health and Human Services to negotiate prices of certain drugs with participating manufacturers in federal healthcare programs. The IRA provides Centers for Medicare & Medicaid Services ("CMS") with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate Medicare reimbursement rates for certain high-cost prescription drug products, which may put limits on prices paid for and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs by government health programs. Additionally, the and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. These price negotiations began in 2023. The IRA requires also provides a new "inflation rebate" covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision will require drug manufacturers to pay rebates a rebate to the federal government if the price for a drug or biologic under Medicare if their drug prices increase Part B and Part D increases faster than the rate of inflation. Effective in 2024, another provision will also eliminate 5% coinsurance for catastrophic coverage under Medicare Part D; while in 2025, Notwithstanding these provisions, the IRA will cap beneficiary annual out-of-pocket expenditure at $2,000 USD. These efforts to reduce aggregate beneficiary spending are expected to shift some costs to drug manufacturers. IRA's impact on commercialization and competition remains largely uncertain.

Other restrictions under applicable federal and state healthcare laws and regulations may include the following:

- the federal Physician Self-Referral Law, which prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, and prohibits the entity from presenting or causing to be presented claims to Medicare for those referred services;
- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, where one purpose is to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of medical device manufacturers;
- the federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal Physician Payments Sunshine Act which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS, certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors); certain other healthcare providers, including physician assistants and nurse practitioners, and teaching hospitals; as well as ownership and investment interests held by physicians and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities that potentially harm customers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to item or services reimbursed by any third-party payor, including commercial insurers; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures and state laws related to insurance fraud in the case of claims involving private insurers.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. We generally depend on our foreign distributors or marketing partners to obtain the appropriate regulatory approvals to market our products in those countries, which may or may not require additional testing for products that have received FDA approval.

However, since medical practice and governmental regulations differ across regions, further testing may be needed to support market introduction in some foreign countries. Some foreign regulatory agencies may require additional studies involving patients located in their countries. Even after foreign approvals are obtained, further delays may be

encountered before products may be marketed. Issues related to import and export can delay product introduction. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

PATENTS, TRADEMARKS AND TRADE SECRETS

We have several trademarks and service marks used on our products and in our advertising and promotion of our products, and we have applied for registration of such marks in the United States and several foreign countries. Most such applications have resulted in registration of such trademarks and service marks.

As of December 31, 2022 December 31, 2023, we owned or had the rights to 30 6 issued patents (4 U.S. and 27 2 foreign) and 4 1 pending foreign applications. application. Patents and patent applications owned or licensed by us include claims to FPC in both dialysate and IV

compositions, formulations and methods of making and parenteral nutritional compositions including Triferic. We have allowed several Charak-licensed and Company-owned patents and applications that are not material to our business to lapse.

Description	United States			Foreign		
	Issued	Expiration	Pending	Issued	Expiration	Pending
Triferic (IV and Dialysate)	3	2027 - 2036 (1), (3)	—	27 (2)	2028 - 2034 (1)	4
Triferic (TPN)	1	2030	—	—		—
Total	4		—	27		4

1. 2029 expiration date in U.S. and 2028 expiration date in foreign (Europe, Japan and Canada) for the synthesis and formulation of our pharmaceutical grade formulation of our Triferic product. In the United States, this patent is listed in Orange Book.
2. One granted European patent validated in 20 European states.
3. US patent for solid particulate composition for use in IV and dialysate will expired in 2036.

Description	United States			Foreign		
	Issued	Expiration	Pending	Issued	Expiration	Pending
Triferic (IV and Dialysate)	3	2027 - 2036	—	2	2028 - 2034	1
Triferic (TPN)	1	2030	—	—		—
Total	4		—	2		1

See Item 1A “Risk Factors” for a discussion of certain risks related to our intellectual property.

Human Capital

As of December 31, 2022 December 31, 2023, we had 253 237 employees, substantially all of whom are full time employees. Our arrangements with our employees are not governed by any collective bargaining agreement. Our employees are employed on an “at-will” basis.

Our key human capital management objectives are to identify, recruit, integrate, retain and motivate our new and existing employees. We believe that our compensation and benefit programs are appropriately designed to attract and retain qualified talent. Employees receive an annual base salary and are eligible to earn a performance-based merit increase and cash bonuses. To create and maintain a successful work environment, we offer a comprehensive package of additional benefits that support the physical and mental health and wellness of all of our employees and their families. Additionally, we grant equity awards in order to allow for enable directors, officers, senior and manager-level employees to share in the performance of the Company.

We are committed to a safe workplace for our employees and have implemented health and safety management processes into our operations. In response to the COVID-19 pandemic, we have implemented additional safety measures continue to follow the CDC protocol for the protection of safe return-to-work for affected employees and remain steadfast in our efforts to keep employees including additional cleaning healthy and protective measures. protected.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk and there can be no assurance that our future results will meet expectations. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, before purchasing our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially and adversely affected. If any of these risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not

presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

RISK FACTOR SUMMARY

- We have limited capital resources and will likely need additional funding before we are able to achieve profitability.
- We may be unable to grow operate and expand our concentrates business, either through acquisitions or organically, which could negatively impact our financial condition and prospects.
- If we are unable to increase our revenue and decrease our expenses, we may need additional funding before we are able to achieve profitability. business. If we are unable to raise additional capital on attractive terms, or at all, we may be unable to sustain grow our operations.
- We Our A&R Loan Agreement with Innovatus contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have been sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.
- Our existing capital resources may continue not be adequate to finance our operating cash requirements beyond the length of time that we have estimated and additional capital that we may need to operate or expand our business may not be affected materially available.
- Our agreement with our largest customer in our concentrates business is set to expire on December 31, 2024 and adversely by increases in raw our inability to negotiate a new agreement would have a material and transportation costs and may be unable to recover certain costs due to provisions in our contracts which provide for fixed prices. Our Products Purchase Agreement with DaVita ends at the end of 2023. If we are unable to extend the relationship adverse effect on favorable terms or at all, our financial condition and results of operations will be materially and adversely affected. operations.
- The ongoing COVID-19 pandemic has resulted in significant disruptions to our business operations, including shortages or disruptions in labor and raw materials Market dynamics in our concentrates business and disruptions that have resulted in lower volumes could lead to the supply chain for pharmaceutical products in our clinical development programs, which could implementation of cost-saving measures that would have a material and adverse effect on our business.
- If our international partners are unable We may fail to or choose not to move forward to obtain regulatory approval in their jurisdictions for Triferic, we will not realize the value anticipated benefits of these relationships. the Evoqua Acquisition, including an improved financial position, and those benefits may take longer to realize than expected.
- If we are unable Our business is highly regulated, resulting in additional expense and risk of noncompliance that can materially and adversely affect our business, results of operations, financial position and cash flows.
- Our business operations may subject us to develop, obtain regulatory approval for, numerous commercial disputes, claims, lawsuits and/or successfully commercialize new therapies leveraging our FPC platform, or if we experience significant delays in doing so, the long-term success of our drug portfolio investigations.
- Our business could be harmed. adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, cybercrime, political crises, geopolitical events, such as the crisis in Ukraine and the Middle East, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

RISKS RELATED TO OUR FINANCIAL POSITION

We have limited capital resources and will likely need additional funding before we are able to achieve profitability operate and expand our business. If we are unable to raise additional capital on attractive terms, or at all, we may be unable to sustain our operations.

We have limited capital resources, a cumulative deficit of approximately $388.8 million $397.2 million since inception and we may incur further losses. As of December 31, 2022 December 31, 2023, we had approximately $21.5 $10.9 million of cash, cash equivalents and investments available-for-sale, and working capital of $17.6 $12.1 million. Net cash used in operating activities for the year ended December 31, 2021 December 31, 2023 was approximately $17.4 $9.4 million.

In March 2020, we entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, ("Innovatus") to make certain term loans to the Company in the aggregate principal amount of up to $35 million. Net draw down proceeds at closing were approximately $21 million, net of estimated fees and expenses. As of December 31, 2022 December 31, 2023, $10 million $8 million remains drawn under the Loan Agreement.

While we expect to have sufficient capital through 12 months from the date of this filing, there is uncertainty beyond that period.

Our ability to fund our planned activities will be dependent upon our ability to restructure our contract contracts with some of our largest customer in customers, raise additional capital, control our concentrates business, enter into new distribution costs and purchase agreements with former Baxter customers, maintain or increase our revenue and lower our expenses in our concentrates business and to raise additional funds in a defined timeline. gross margin on sales. These factors are subject to significant risks and uncertainties and there can be no assurance that we will be successful in raising additional capital, controlling costs and restructuring our contract with our largest customer and

entering into new contracts with former Baxter customers. relationships. If we are unable to achieve one or all of these objectives, we may be forced to implement further cost-saving measures that could have a negative impact on our activities. If we are unable to restructure current or enter into new contracts in our concentrates business, increase our revenues and decrease our expenses or raise any required capital, we may be forced to curtail our activities and, ultimately, cease operations. In addition, our day-to-day operations depend in part on the amount of credit our suppliers will extend to us. If we are unable to maintain a favorable financial position, that credit may be curtailed, which could significantly impact our operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

Our A&R Loan Agreement with Innovatus contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

Pursuant to the A&R Loan Agreement, we have pledged substantially all of our assets and the assets of our subsidiary, Rockwell Transportation, Inc., and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Innovatus. Additionally, the Loan Agreement contains customary representations and warranties and affirmative covenants, subject to customary carve outs, and includes financial covenants related to liquidity and actual concentrates hemodialysis products revenue (measured on a quarterly biannual basis). The A&R Loan Agreement also contains negative covenants that, among other things, restrict our ability to:

- incur additional indebtedness;
- grant liens;
- make distributions, including dividends;
- enter into a merger or consolidation;
- alter the business of the Company; or
- sell all or a portion of the Company's property, business or assets.

These terms of the A&R Loan Agreement could prevent us from taking certain actions without the consent of our lenders, which may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders, placing us at a competitive disadvantage compared to our competitors who have less leverage and who therefore may be able to take advantage of opportunities that our leverage prevents us from exploiting. These covenants could also limit our ability to make needed capital expenditures or otherwise conduct necessary or desirable business activities.

If we cannot maintain compliance with the covenants under our A&R Loan Agreement, we may trigger an event of default. Our ability to comply with these covenants may be adversely affected by events beyond our control. For example, in September 2021, we entered into an amendment to the Loan Agreement in which the Company, in exchange for Innovatus lowering the sales covenants (then based upon Triferic sales), agreed to (i) prepay an aggregate principal amount of $7.5 million in ten installments commencing on December 1, 2021; (ii) pay an additional prepayment premium of 5% on prepaid amounts if the Company elects to prepay all outstanding term loans on or before September 24, 2023 and (iii) maintain minimum liquidity of no less than $5 million if the aggregate principal amount of term loans is greater than $15 million pursuant to the liquidity covenant in the Loan Agreement. On November 10, 2022, the Company we entered into the Second Amendment to Loan Agreement under which the Company we (i) prepaid an aggregate principal amount of $5.0 million in outstanding term loans in one installment on November 14, 2022; (ii) agreed to make interest-only payments until September 2023 at (at which time the Company will resume we resumed scheduled debt payments payments) in consideration for certain modifications to the financial covenants under the Loan Agreement. As The A&R Loan Agreement provides for us to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The loan will mature on January 1, 2029, unless earlier repaid. The A&R Loan Agreement includes a financial covenant that requires actual consolidated revenue from the sale and supply of December 31, 2022 hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 85.0% of the Company was projections for the same period and, beginning with the quarter ending September 30, 2024, actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 80.0% of the projections for the same period. The A&R Loan Agreement also includes a liquidity covenant that requires that us to maintain minimum liquidity of the greater of (x) our three-month cash burn or (y) the sum of $1.5 million and the aggregate amount of capital lease payments required to be made during the succeeding 12 months (or during a continuing event of default, the aggregate amount of capital lease payments required to be made during the entire term of such capital leases). Although we are currently in compliance with all reporting and financial covenants, but there can be no assurance that we will be able to continue to maintain compliance in the future.

The A&R Loan Agreement also includes customary events of default, including, among other things, a change of control or a failure to comply with certain of the covenants in the A&R Loan Agreement. Upon the occurrence and continuation of an event of default, all amounts due under the A&R Loan Agreement become (in the case of a bankruptcy event), or may become (in the case of all other events of default and at the option of Innovatus), immediately due and payable.

If an event of default under the A&R Loan Agreement should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the A&R Loan Agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business and financial condition.

Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated and additional capital that we may need to operate or expand our business may not be available.

Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to:

- the timing of any restructuring extension of the contract with our largest customer in our concentrates business;
- our ability to enter into new contracts and negotiate favorable terms with former Baxter our customers;
- our ability to increase our prices to keep up with inflation;
- whether we experience significant input costs for, or disruptions to, the manufacturing or distribution of our products;
- whether we expand into new territories; and
- our international partners' commitment whether we develop and ability to obtain regulatory approval for Triferic in their countries. launch new product offerings.

If we are required to raise additional capital to fund our operations, such equity financings may be dilutive to our stockholders and newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. Any debt financing is limited by the terms of our Securities Purchase Agreement with DaVita, dated as of April 6, 2022, pursuant to which they invested in our convertible preferred stock. Specifically, until DaVita owns less than 50% of its investment, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $5 million or to refinance existing debt, unless DaVita consents.

Debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business. If our operations or development activities require substantial cash resources in the future in excess of our liquid resources on hand and if our cash flows are not sufficient to support financing through unsecured indebtedness, we may not be able to obtain debt financing and our capital financing options may become limited.

Regardless of whether we seek to raise additional working capital through the sale of equity securities or the incurrence of indebtedness, if we do not have sufficient funds available to run our concentrates business and pursue business opportunities, our business, results of operations, financial position and cash flowscould be materially adversely affected.

Our revenue growth and profitability projections are based on various assumptions that may not come to fruition.

Our revenue growth and profitability projections are subject to many assumptions regarding our future operations, including that we are successful in expanding to new territories, that we successfully develop and launch new product offerings, that we are able to increase our prices to keep up with inflation, and that we do not experience significant disruptions to the manufacturing or distribution of our products, among other assumptions. If we are unsuccessful in one or more of those efforts, we may not be able to achieve our projected growth and profitability.

RISKS RELATED TO OUR BUSINESS

Our agreement with our largest customer in our concentrates business is set to expire on December 31, 2023 December 31, 2024 and our inability to negotiate a new agreement would have a material and adverse effect on our financial condition and results of operations.

Our Amended and Restated Products Purchase Agreement (the "Products Purchase Agreement") with DaVita is set to expire on December 31, 2023 December 31, 2024. The Products Purchase Agreement is a fixed price agreement that contains a number of limitations on our ability to raise prices. agreement. In April 2022, September 2023, we amended our the original Products Purchase Agreement with DaVita to raise our prices in light of inflationary pressures. However, rising costs pressures and declining volumes ordered by DaVita since April 2022 have had and could continue to have a negative impact on our business. remove certain provisions. The Products Purchase Agreement requires ninety (90) days' notice of non-renewal upon expiration. If may be extended by DaVita for one year in its sole discretion. When the Products Purchase Agreement is again up for renewal, we are may be unable to reach an agreement with DaVita on new terms that make economic sense for us, us. In that case, we do would not expect to enter into a new agreement. This would result in the loss of approximately one-half of our current volume of concentrates products and would have a material and adverse effect on our financial condition and results of operations and would likely lead to the implementation of cost saving measures that would negatively impact our activities.

Market dynamics in our concentrates business that have resulted in lower fluctuating volumes that could lead to the implementation of cost saving cost-saving measures that would have a material and adverse effect on our business.

Volumes have been decreasing fluctuated in our concentrates business, due to the reduction in patient census caused by COVID-19 and cost saving measures by our customers. customers, including switching to single use bicarbonate canisters. If these volumes decrease further, substantially, we may be forced to consolidate our operations and curtail our activities to lower our fixed costs. While our fixed costs would be reduced by such actions, we may not be able to realize the full amount of that reduction if our variable costs (such as transportation) increase and we are unable to pass along those increases to our customers. In addition, a consolidation or restructuring of our business could lead to significant one-time costs related to exiting operations. Such a consolidation could have a material and adverse effect on our business, financial condition and results of operations.

Our reacquisition of distribution rights for our concentrates products from Baxter through the termination of our Exclusive Distribution Agreement has many attendant risks and may not result in the financial outcome we expect.

In 2022, we terminated our Exclusive Distribution Agreement with Baxter and reacquired the distribution rights related to our concentrates products for Baxter's portfolio of clinics. Our Distribution Agreement with Baxter enabled us to charge Baxter an amount above cost for our concentrates products, while limiting us to a capped percentage of sales for the transportation costs associated with delivering those products. Now that we have assumed full responsibility for selling and delivering our concentrates products to former Baxter customers and any other customers we may add, we bear all financial and other risk associated with the business. We may lose former Baxter customers if we need fail to

increase realize the prices anticipated benefits of our concentrates products due the Evoqua Acquisition, including an improved financial position, and those benefits may take longer to rising costs or for other reasons. In addition, since we agreed to charge certain customers a fixed cost through March 31, 2023 realize than expected.

On July 10, 2023, we may lose money if those fixed costs do not cover completed our actual costs. We also may be unable to renegotiate unprofitable contracts with certain customers. In addition, because we do not have access to all acquisition of the distribution channels Baxter utilized for our products, we may lose certain customers if we cannot find a suitable alternative channel by which hemodialysis concentrates assets (the “Evoqua Acquisition”) from Evoqua. Our synergistic goals with regard to serve them. Each of these scenarios could result in the business we reacquired generating less revenue or less profit than we expect acquisition include an improved financial position, expanded geographic footprint, customer base and could adversely impact our financial condition or results of operations.

Unfavorable weather, economic conditions or supply shortages could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general weather conditions, as well as conditions in the United States product offerings, and global economy and in the global financial markets. A severe weather or other geological event in our locations or those of our suppliers, or prolonged economic downturn or persistent inflation have and could continue to result in a variety of risks to our business, including our ability to recover our costs or to raise additional capital when needed on acceptable terms, if at all. In addition, weather-related events may jeopardize our ability to deliver our products as required by our contracts. For example, after Hurricane Ian severely damaged parts of the Florida Gulf Coast, many roads and bridges were destroyed. While we were able to make our deliveries after the storm, that may not always be the case. A weak or declining United States or global economy could also strain our suppliers, possibly resulting in supply disruption. In addition, due to macro-economic conditions in the global economy, there have been shortages in raw materials, parts and fuel that we need to run our business. Recently, our suppliers have experienced shortages in bicarbonate and acid, which are components of our dialysis concentrates, and parts needed for our equipment to make certain of our products. Diesel fuel has also been in short supply in the United States and our delivery trucks run on diesel. increased manufacturing capacity. While we have been able to minimize completed the impact integration of these disruptions to date, Evoqua’s former assets, there can be no assurance that we will continue. Any be able to operate Evoqua’s former product line profitably. In addition, many of the foregoing former Evoqua customers that we inherited as a result of the Evoqua Acquisition are not subject to contractual purchasing commitments and may discontinue their business with us as a result of the transition of ownership.

Following the Evoqua Acquisition, the number of our customers is significantly larger than prior to the Evoqua Acquisition. The Company's future success depends, in part, upon our ability to manage this expanded business, which will pose substantial challenges for our management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. The dedication of management resources to this portion of our business could detract attention from our current day-to-day operations.

Because we have limited financial resources, by investing in the Evoqua Acquisition, we may forgo or delay pursuit of other future opportunities that may have proven to have greater commercial potential. Also, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Evoqua Acquisition. Further, it is possible that undisclosed, contingent, or other liabilities, problems or obligations may arise in the future of which we were previously unaware. These disclosed and undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations.

These factors, including the failure of the expanded business to perform as expected, could decrease or delay the expected accretive effect of the Evoqua Acquisition, negatively affect our stock price, result in impairment of our intangible assets, and harm our financial condition, results of operations or business and we prospects. As a result, it cannot anticipate all be assured that the Evoqua Acquisition will result in the full realization of the ways benefits anticipated from the Evoqua Acquisition or in which the anticipated time frames or at all.

We depend on a third party to manufacture products for the business that was the subject of the Evoqua Acquisition. If this organization is unable or unwilling to manufacture our newly acquired concentrates products, or if the organization fails to comply with applicable regulations or otherwise fails to meet our requirements, our business will be harmed.

We rely on a contract manufacturing organization ("CMO") to manufacture the concentrates products that were the subject of the Evoqua Acquisition. If that CMO is unable to manufacture those products in sufficient quantities and on a consistent basis, or if it becomes unwilling to produce the products for us, we may not be able to fulfill our contractual requirements or sell those products while we look for an alternative. We currently have a single-source supplier, and our supply contract expires at the end of 2024. If we were to experience a supply disruption, it could take an extended period of time to take over the manufacturing ourselves. The manufacturing facilities and processes used by our CMO must be approved by the FDA before the products manufactured by such CMO can be sold. After approval, our CMO must meet certain ongoing regulatory requirements for product testing and stability of commercially marketed products. We do not control the manufacturing processes of our CMO and depend on it to comply with current economic climate good manufacturing practices (“cGMP”) and financial market conditions obtain and maintain regulatory approval. If approval for a CMO is not received or ongoing testing does not continue to meet approved standards and approval is withdrawn, the CMO’s production would be delayed or suspended, which could adversely impact affect our business. If that was to happen, we may be forced to find another capable CMO or take over production ourselves. Any such circumstance could significantly hamper our ability to supply our customers in a timely manner, which may have a material adverse effect on our financial condition and results of operations.

We have been and may continue to be affected materially and adversely affected by increases in raw material, labor and transportation costs and may be unable to recover certain costs due to provisions in our material contract. largest customer contract and other fixed price contracts and we may lose other customers due to price sensitivity.

A significant portion of our costs relates to chemicals and other raw materials and transportation, which such costs are out of our control, and we may not be able to recover a portion of such costs due to provisions in our material contract the Products Purchase Agreement with DaVita. DaVita and other fixed price contracts. The costs of chemicals and other raw materials are subject to price volatility based on supply and demand and are highly influenced by the overall level of economic activity in the United States and abroad. In addition, labor costs have been steadily rising and our manufacturing process is labor intensive, which increases our costs to produce our products.

These costs have tended to rise from year to year and are likely to continue to rise in the future. In the past year, raw materials costs have increased significantly, due to short supply and excess demand. In addition, in many areas, we have a single source of raw materials, which makes us particularly sensitive to cost increases. Transportation also comprises a significant portion of our costs. We have been adversely affected by a general shortage in commercial truckers in the United States and significant increases in labor and fuel costs. In addition, as mentioned above, there has, in the past, been a nationwide shortage of diesel fuel in the United States, which we use to run our delivery trucks. Such a shortage, has and in the future may result in an increase in the cost of diesel fuel or lack of availability of diesel fuel and we would need to find another way to deliver our products

to clinics. If we are unable to do so, we could be in breach of our contracts. In addition, any increase in the use of third-party freight would significantly increase our costs, which we may not be able to pass on to our customers.

Our Product Purchase Agreement with DaVita provides for a fixed price to DaVita, with limited increases from year to year that must be agreed to by the parties, regardless of the increases in raw materials costs and transportation costs. As a result, we have in the past been unable to fully recover our costs for the products we sell to DaVita (including transportation costs). This has had and could in the future have a material and adverse impact on our financial position. On April 6, 2022, we entered into an amendment to the Products Purchase Agreement under which we agreed to a price increase, effective May 1, 2022, as well as the pass-through of certain costs (subject to a cap), which are determined on a quarterly basis. Continued rising costs and declining volumes have had and could continue to have a negative impact on our business. In addition, if our costs exceed an overall cap, the Products Purchase Agreement may be subject to termination by DaVita.

We expect that if we continue to be subject to the limitations in the Products Purchase Agreement and other fixed price contracts, the increasing costs and decreasing volumes may continue to negatively impact our profit margins and materially and adversely affect our financial position.

Some of our customers buy products from us on a purchase order basis or pursuant to contracts that allow for price increases at least once per year. In situations where we are able to increase prices to keep up with our costs, we may lose customers if such customers are unwilling to pay higher prices. That would result in lost revenue for the Company and may negatively impact our financial position and results of operations.

A few customers account for a substantial portion of the end user sales of our concentrate products. The loss of any of these customers could have a material materially and adverse effect on adversely affect our business, results of operations, financial position and cash flows.

Sales of our medical device products are highly concentrated in among a few customers. One customer accounted for nearly half of our sales in each of the last three years and for a substantial number of the clinics we serve. Due to the composition of Evoqua's customer portfolio, we experienced further concentration with regard to that customer and an additional customer through the Evoqua Acquisition. The loss of any of these significant customers could have a material adverse effect on materially and adversely affect our business, results of operations, financial position and cash flows.

Unfavorable weather, economic conditions or supply shortages could materially and adversely affect our business, financial condition or results of operations.

Our results of operations could be materially and adversely affected by general weather conditions, as well as conditions in the United States and global economy and in the global financial markets. A severe weather or other geological event in our locations or those of our suppliers, or prolonged economic downturn or persistent inflation have and could continue to result in a variety of risks to our business, including our ability to recover our costs or to raise additional capital when needed on acceptable terms, if at all. In addition, weather-related events may jeopardize our ability to deliver our products as required by our contracts. For example, in 2023, winter storms led to delays in our operations, particularly in the transportation division as equipment froze and roads became impassible. A weak or declining United States or global economy could also strain our suppliers, possibly resulting in supply disruption. In addition, due to macro-economic conditions in the global economy (including inflation), there have been shortages in raw materials, parts and fuel that we need to run our business. For example, from time to time, our suppliers have experienced shortages in bicarbonate and acid, which are components of our dialysis concentrates, and parts needed for our equipment to make certain of our products. Diesel fuel has also been in short supply in the United States at times and our delivery trucks run on diesel. While we have been able to minimize the impact of these disruptions to date, there can be no assurance that will continue. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We face competition in the concentrate concentrates market and have a large competitor with substantial resources.

The primary competitor in the market for our concentrate concentrates products is Fresenius, a large, diversified company which has financial, technical, manufacturing, marketing, research and management resources substantially greater than ours. We may not be able to successfully compete with Fresenius. Fresenius has historically used product bundling and low pricing as a competitive strategy to capture market share of concentrate concentrates products. We may be at a disadvantage in competing against these strategies to sell concentrate concentrates products. Furthermore, Fresenius is vertically integrated and is the largest provider of dialysis services in the United States, treating approximately 37% of all U.S. in-center hemodialysis patients through its clinics. Fresenius has routinely acquired our customers, and it may acquire more of our customers in the future. In addition to Fresenius, we are aware of other large manufacturers potentially looking to increase their market share of the domestic concentrates market, which, if successful, could have an impact upon our profitability.

Our production and other processes are largely manual, which introduces risk of error and may result in rising production costs.

The production of our hemodialysis concentrates products is largely manual and involves considerable unskilled labor. The manual nature of production can introduce the risk of error. In addition, manual processes involving high amounts of labor can result in significant production costs. Many of our products are "made to order," which can further increase production costs as we have to frequently change production runs. Unless we are able to automate our production processes, our costs may continue to increase and we may be unable to recover those rising costs or may lose customers altogether, which could negatively impact on our financial position.

Our business depends on government funding of health care, and changes could impact our ability to be paid in full for our products, increase prices or cause consolidation in the dialysis provider market.

Medicare and Medicaid fund the majority of dialysis costs in the United States. Many dialysis providers receive the majority most of their funding from the government and are supplemented by payments from private health care insurers. These providers depend on Medicare and Medicaid funding to be viable businesses. Changes to health insurance and reimbursement by Congress may have a negative impact on Medicare and Medicaid funding and on reimbursement protocols. If Medicare and Medicaid funding were to be materially decreased, decrease, dialysis providers would be severely impacted, increasing our risk of not being paid in full. An increase in our exposure to uncollectible accounts could have a material adverse effect on our business, results of operations, financial position and cash flows.

Since 2011, CMS has continued to modify reimbursement policies for dialysis under the end-stage renal disease ("ESRD") prospective payment system generally falling short of covering the increasing cost of dialysis care resulting in economic pressure of dialysis providers. We anticipate that dialysis providers will continue to seek ways to reduce their costs per treatment due to these reimbursement policies, which could reduce our sales and profitability and have a material adverse effect on our business, results of operations, financial position and cash flows.

Federal and state healthcare reform measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, or change the methods used by Medicare and Medicaid to reimburse providers, including the “bundled” payment model. Any such reforms could potentially impact reimbursement by Medicare and Medicaid programs for dialysis and could negatively affect the ability of certain individuals to obtain coverage.

As a result of these changes to Medicare and Medicaid reimbursement, the dialysis provider industry may continue to consolidate. This may result in increased purchasing leverage for providers across all dialysis product categories and increased pricing pressure on all suppliers to the industry.

Our medical device products are life sustaining and any failure to supply them to our customers and resulting scrutiny related to such circumstances could negatively impact our reputation and stock price.

Our hemodialysis concentrates products are critical to sustain the lives of patients who need them.Routine business actions we take under our contractual arrangements with purchasers or individual clinics, such as price increases or discontinuation of supply to customers who fail to pay us on time or at all, could mean that our customers may need to find alternative sources of supply and may not be able to serve their patients.This may result in increased governmental or other scrutiny on our business.Such actions could also result in reputational harm to us and have a negative impact on our stock price.

We may not be successful in expanding our concentrates business or our drug product portfolio or in our business development efforts related to in-licensing, acquisitions or other business collaborations. Even if we are able to enter into business development arrangements, they could have a negative impact on our business and our profitability.

We In addition to the Evoqua Acquisition, we may seek to make further acquisitions or enter into business development arrangements in our concentrates business to expand our customer base or geographic footprint. In addition, as part of our business strategy, to expand our drug product portfolio, we may seek to acquire or in-license other drug products or product candidates that we believe are a complementary fit with our current product candidate portfolio, business, as well as other product or product candidates that we believe have substantial development potential. We may not be able to identify such opportunities. If we do, the negotiation of such arrangements can be a lengthy, complex and expensive process and there can be no assurance that any such negotiations will be completed on a timely basis or at all or result in an arrangement that will enable us to effectively integrate, develop and launch such products or product candidates effectively.

In addition, the market potential for new drug products or product candidates is highly uncertain and evaluation of such potential requires significant judgment and assumptions. There is a significant risk that any new drug product may not be able to be brought to market as profitably as expected or at all. If the results of any new drug product initiative are materially worse than expected, it could have a material adverse effect on our business, results of operations, financial position and cash flows.

Our international partnerships for Triferic involve risks that may materially impact those international relationships or our business generally.

We rely on third party suppliers have international partnerships for raw materials Triferic that require us to supply the drug product to be marketed and packaging components of our drug products that we supply and will supply to our international partners. We may not be able to obtain the raw materials and proper components we need, or the cost of the materials or components may be higher than expected, any of which could impair our production or commercialization of drug products for our international partners and have a material adverse effect on our relationships with our international partners.

sold in foreign countries. We may not be able to obtain the raw materials or packaging components we need to supply our international partners, or the price of such materials or components may rise significantly, for a variety of reasons, including but not limited to:

- to a business interruption, including a force majeure, cyber-attack, labor strike at a supplier, a COVID-related halt or slowdown of supply increased costs of raw materials, or production of components;
- global supply chain delays or disruptions;
- regulatory requirements or action by regulatory agencies or others against a supplier, including delays in receiving necessary approvals;
- failure of a supplier to comply with cGMP standards, which could result in quality or product failures, adulteration, contamination and/or recall;recall and other factors beyond our control.
- adverse financial or other strategic developments at or affecting a supplier;
- termination or disagreement over the terms and conditions of the supply contract by a supplier or our inability to comply with the minimums in such an agreement;
- unexpected demand for or shortage of raw materials or packaging components; and
- unexpected increases in our product demand.

Some of the suppliers for our raw materials or packaging components are single-source suppliers. If those suppliers were unable to supply us for any reason, including the reasons mentioned above, we could experience cost increases or supply interruptions. Finding an alternative source can be expensive and take a substantial amount of time, especially when regulatory approval is required to qualify the supplier. If we are unable to obtain our raw materials and packaging components and are not able to establish alternative supply sources, or if the prices for such items increase substantially, our CMOs may not be able to produce the desired quantities of our drug products for our international partners and our relationships may be materially adversely affected.

We In addition, the third parties that we depend on third parties to manufacture Triferic for our international partners. If these organizations are partners may be unable or unwilling to manufacture our drug products, or if these organizations fail to comply with applicable regulations or otherwise fail to meet which could also harm our requirements, our business relationships with our international partners will be harmed.

We rely on CMOs to manufacture Triferic for our international those partners. If a CMO is unable to manufacture Triferic in sufficient quantities and on a consistent basis, or if it becomes unwilling to produce Triferic for us, we may not be able to supply our international partners in a timely or cost-effective manner. For Triferic (dialysate) and Triferic AVNU, we have a single-source finished goods supplier and do not have a long-term supply contract. If we were to experience a supply disruption, it could take an extended period of time to find and qualify an alternate supplier. The manufacturing facilities and processes used by our CMOs must be approved by the FDA and foreign regulators, where applicable, before the drug products manufactured by such CMOs can be sold. After approval, CMOs must meet certain ongoing regulatory requirements for product testing and stability of commercially marketed products. We do not control the manufacturing processes of our CMOs and depend on them to comply with current good manufacturing practices (“cGMP”), cGMP, and obtain and maintain regulatory approval. If approval for a CMO is not received or ongoing testing does not continue to meet approved standards and approval is withdrawn, the CMO’s production would be delayed or suspended, which could adversely affect our international partner’s partners’ Triferic commercialization efforts. If that was to happen,

Finally, we may be forced to find another capable CMO or shift production to another CMO that is already approved and under contract with us. Any such circumstance could significantly hamper our ability to supply our customers with our drug products in a timely manner, which may have a material adverse effect on our international business relationships.

We may not be successful in arranging out-licensing partners capable of obtaining the approvals needed to effectively commercialize Triferic (dialysate), Triferic AVNU or any other drug product candidates outside of the United States. Even if our international partners are successful in obtaining the required regulatory approvals, they may not be effective at marketing our drug products in certain markets or at all.

The regulatory procedures for obtaining marketing approval of drug products and product candidates, including Triferic (dialysate) and Triferic AVNU, outside the United States vary from country to country and such approvals can be difficult to obtain. Our strategy is to out-license the rights to our drug products in markets outside the United States to partners who we believe will have the necessary resources and expertise to obtain regulatory approval and ultimately commercialize our out-licensed drug products. However, we may not be successful in finding new partners who will be willing to invest in our drug products outside the United States and even if we are able to find new partners, they may not be able to obtain the necessary foreign regulatory approvals. Our international partners may decide not to move forward with clinical trials or other steps necessary for foreign regulatory approval, which could result in their failure to meet milestones and the loss of potential revenue to us. If we are not successful in out-licensing our drug products outside of the United States or entering into other arrangements with partners capable of obtaining the necessary regulatory approvals to commercialize our drug products or if our current international partners delay or cease their efforts, we may decide to delay or abandon development efforts in certain markets. Any such delay or abandonment, or any failure to receive one or more foreign approvals, may have an adverse effect on the benefits otherwise expected from marketing in foreign countries and may result in the violation of our license agreements.

If we are successful in obtaining partners to develop and commercialize our drug products in foreign markets, we will be dependent upon their effectiveness in selling and marketing our drug products in those foreign markets. These partners may face stiff competition, government price regulations, generic versions of our drug products, violations of our intellectual property rights and other negative events or may otherwise be ineffective in commercializing our drug products, any of which could reduce the market potential for our drug products and our success in those markets.

If Triferic or any other drug product candidates are approved and marketed outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We may be subject to additional risks due to Triferic or any other drug product candidates being approved and marketed outside of the United States, including:

- increased cost or resource requirements associated with measures required to support the registration and/or sale of the product or products, such as labeling changes, product changes, testing, provision of documents or production requirements;
- unexpected changes in the safety profile;
- reduced protection for intellectual property rights;
- additional risk of litigation;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with anti-corruption laws, including the Foreign Corrupt Practices Act (the “FCPA”);
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- business interruptions resulting from disease outbreaks, including the recent coronavirus disease epidemic, pandemics, geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires.

If we do not successfully manage these risks, our prospects related to marketing products or product candidates Triferic outside the United States by our international partners could suffer.

We have in-licensed rights to certain patents that cover Triferic. If we fail to remain in compliance with these license agreements, we could forfeit the rights to these patents, which could negatively impact our partners' ability to commercialize our products and result in our noncompliance with those partnership agreements.

We have acquired rights to certain patents under license agreements, including from an affiliate of Dr. Ajay Gupta, our former Chief Scientific Officer. These in-licensed patents, if granted, cover Triferic AVNU and have other claims that could cover Triferic. If we fail to remain in compliance with the terms of these license agreements, including due diligence obligations relating to our efforts to develop and commercialize licensed products in certain markets, we could be found to be in breach of these license agreements. If this was to happen, the licensor could terminate the license agreement in certain circumstances, causing us to forfeit our rights to the licensed patents. This could cause us to lose the ability to sell certain products, including Triferic and Triferic AVNU, and could potentially subject us to expensive and protracted litigation. Such an event would also result in our failure to comply with our distribution agreements with our international partners. Any of these occurrences could significantly harm our results of operations.

Our business and operations would suffer in the event of a security breach, system failure, invasion, corruption, destruction or interruption of our or our business partners’ critical information technology systems or infrastructure.

In the ordinary course of business, we and our business partners store sensitive data, including intellectual property and proprietary information related to our business, our customers and our business partners, on our information technology systems. Despite the implementation of security measures, these systems are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication, electrical and other system failures due to employee error, malfeasance or other disruptions. We could experience a business interruption, monetary loss, intentional theft of confidential information or reputational damage, including damage to key customer and partner relationships, from system failures, espionage attacks, malware, ransomware or other cyber-attacks. Such cyber-security breaches may compromise our system infrastructure or lead to data leakage, either internally or at our contractors or consultants. The risk of a security breach or disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. From time to time, we are subject to phishing attempts. In the fourth quarter of 2023, we discovered a business email compromise caused by phishing. We do not believe that it had a material adverse effect on our

business. We implemented remedial measures promptly following this incident; however, we cannot guarantee that those remedial measures will prevent additional related, as well as unrelated, incidents.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, we could be subject to legal claims or proceedings, liability under laws and regulations governing the protection of health and other personally identifiable information and related regulatory penalties. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future.

We are highly dependent on the operations, product development, clinical and business development expertise of the principal members of our management, operations and clinical team. We have hired executive-level employees who are leading Company initiatives, including its operational initiatives. Although we have entered into employment agreements with our executives and key employees, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified manufacturing, sales and marketing, scientific, and clinical personnel is critical to our success. The loss of the services of our executive officers or other key employees could seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time due to the overall state of the labor pool and the difficulty finding the specialized skills we require. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous medical device, pharmaceutical and biotechnology companies for similar personnel.

Finding production associates for our manufacturing facilities and truck drivers for our transportation division has also presented challenges for us. There is similarly a great deal of competition for these workers. This competition has resulted in increasing compensation costs as we attempt to attract and retain workers.

Our business and operations would suffer in the event of a security breach, system failure, invasion, corruption, destruction or interruption of our or our business partners’ critical information technology systems or infrastructure.

In the ordinary course of business, we and our business partners store sensitive data, including intellectual property and proprietary information related to our business, our customers and our business partners, on our information technology systems. Despite the implementation of security measures, these systems are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication, electrical and other system failures due to employee error, malfeasance or other disruptions. We could experience a business interruption, monetary loss, intentional theft of confidential information or reputational damage, including damage to key customer and partner relationships, from system failures, espionage attacks, malware, ransomware or other cyber-attacks. Such cyber-security breaches may compromise our system infrastructure or lead to data leakage, either internally or at our contractors or consultants. In particular, system failures or cyber-security breaches could result in the loss of nonclinical or clinical trial data from completed, ongoing or planned trials, which could cause delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The risk of a security breach or disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, we could be subject to legal claims or proceedings, liability under laws and regulations governing the protection of health and other personally identifiable information and related regulatory penalties. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

We use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We use hazardous materials, which could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair the operation of our pharmaceutical business and any development or expansion efforts.

In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment would be covered by our workers’ compensation insurance policy. However, we do not carry specific hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, or operations otherwise affected.

RISKS RELATED TO OUR PRODUCT CANDIDATES

The long-term success of our drug product portfolio depends on our ability to leverage the FPC platform to develop new therapies in disease states that currently have an unmet need for management of iron deficiency or iron deficiency anemia. If we are unable to develop, obtain regulatory approval for or successfully commercialize these new therapies, or if we experience significant delays in doing so, our business prospects could be harmed.

Successful development and ultimate regulatory approval of new therapies based on our FPC platform in disease states outside of ESRD where iron replacement is required is important to our business prospects. We conducted an evaluation of the potential utility of FPC in certain disease states and believe that, based on the results of this analysis, FPC would be viable. However, there is no assurance that our findings regarding the clinical and commercial viability of FPC are accurate or provide a complete portrayal of the medical and commercial challenges FPC will face. Furthermore, new legislation, reimbursement guidance, regulatory requirements or medical developments may negatively impact our conclusion that FPC is economically and clinically viable.

The development of new therapies is lengthy, time-consuming and expensive. We expect to incur substantial expense for both preclinical studies and clinical trials with no guarantee that these efforts would either be completed in a timely manner or that they would result in a positive outcome. Completion of clinical trials may take several years or

more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product. Factors that can influence and affect the rate of completion of clinical trials include the potential delay by a partner in beginning a clinical trial, the failure of third-party contract research organizations ("CROs") and other third-party service providers and independent clinical investigators to manage and conduct the trials properly, to perform their oversight of the trials or to meet expected deadlines, the inability to recruit clinical trial participants at the expected rate, the inability to follow patients adequately after treatment, unforeseen safety issues and unforeseen governmental or regulatory issues or concerns, including those of the FDA, DEA and other regulatory agencies. For example, we submitted an IND for FPC to be used in the home infusion setting and based upon the feedback we received from the FDA, we determined to put the program on hold due to the time and expense that would be required to satisfy the FDA's concerns.

We expect that we will need to raise additional funds to develop new therapies based on our FPC platform. We may not be able to obtain or secure the funding necessary to complete such development or initiate or complete the necessary clinical trials. In addition, there is no assurance that such funding will be available to us or that it will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. Any failure to raise capital as and when needed could have a negative impact on our ability to pursue our business plans and strategies related to our FPC platform.

If we are unable to obtain and maintain adequate protection for our data, intellectual property and other proprietary rights, our FPC asset may be harmed.

The value of our FPC platform depends in part on our ability to obtain and defend patent and other intellectual property rights that are important to the commercialization of our drug products and product candidates. The degree of patent protection that will be afforded to our drug products and processes in the United States and in other important markets remains uncertain and is dependent upon the scope of protection afforded to us by the patent offices, courts, administrative bodies and lawmakers in the relevant jurisdictions. We can provide no assurance that we will successfully obtain or preserve patent protection for the technologies incorporated into our drug products and processes, or that the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business. If we cannot prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect.

While we have an issued patent in the United States and certain other major markets, including Europe and Japan, that covers the I.V. and Dialysate formulations of Triferic, these patents expire in 2028 in Europe and Japan and 2029 in the United States. The previously issued foundational composition-of-matter patents for Triferic expired in 2016. In light of the current patent protection that we have for Triferic, it is possible that a competitor could seek to manufacture a generic version of Triferic using product specifications and manufacturing methods that do not infringe our issued patent. Further, it is possible that a competitor could seek to invalidate our issued Triferic patent.

We also rely on regulatory exclusivity for protection of our drug products, which includes regulatory data protection and market protection. Implementation and enforcement of regulatory exclusivity varies widely from country to country. The failure of our international partners to qualify for regulatory exclusivity, or failure to obtain or maintain the necessary extent or duration of such protections for our drug products could affect our decision on whether to seek a partner to market our drug products in a particular country.

Litigation, interferences, oppositions, *inter partes* reviews, administrative challenges or other similar types of proceedings are, have been and may in the future be necessary to determine the validity and scope of certain of our proprietary rights. Such proceedings may also be necessary to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our drug products. We may also face challenges to our patent and regulatory protections covering our product candidates by third parties.

Litigation, interference, oppositions, *inter partes* reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our drug products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. An

adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from developing, manufacturing or selling our product candidates. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

We have in-licensed rights to certain patents that cover our FPC products. If we fail to remain in compliance with these license agreements, we could forfeit the rights to these patents, which could negatively impact our partners' ability to commercialize our products and our ability product candidates.

We have acquired rights to certain patents under license agreements, including from an affiliate of Dr. Ajay Gupta, our former Chief Scientific Officer. These in-licensed patents, if granted, cover Triferic AVNU and have other claims that could cover Trifericand other product candidates. If we fail to remain in compliance with the terms of these license agreements, including due diligence obligations relating to our efforts to develop and commercialize licensed products in certain markets, we could be found to be in breach of these license agreements. If this was to happen, the licensor could terminate the license agreement in certain circumstances, causing us to forfeit our rights to the licensed patents. This could cause us to lose the ability to sell certain products, including Triferic and Triferic AVNU, and could potentially subject us to expensive and protracted litigation. Any of these occurrences could significantly harm our results of operations and future prospects.

RISKS RELATED TO REGULATORY APPROVALS

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("IRA"), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related

healthcare reforms. We cannot be sure whether additional legislation or rule making related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for our FPC pipeline product candidates would limit our prospects and harm the long term viability of our drug portfolio.

We do not expect our FPC pipeline product candidates to be commercially available for several years, if at all. Our future product candidates will be subject to strict regulation by regulatory authorities in the United States and in other countries.

The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities, which may, among other things, interpret data differently. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of our FPC pipeline product candidates will ever obtain regulatory approval. Our future product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities for many reasons. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of the product candidate.

Even if we obtain regulatory approval for one of our FPC pipeline product candidates, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product,

such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall, withdrawal of the product from the market, suspension of manufacturing or other actions.

Even if our FPC pipeline product candidates receive regulatory approval, they may still face future reimbursement challenges.

If approved, reimbursement of our FPC pipeline product candidates by Medicare and commercial payers will be integral to their ability to be a commercial success. While we attempt to incorporate factors such as marketing strategy and payer reimbursement into our clinical trial decision making, these decisions must be balanced against the time and resources required to demonstrate a benefit, the increased complexity of development and manufacturing and the potential delays to approval of the lead indication. While we try to plan clinical trials appropriately to foresee such challenges, there is no guarantee that unexpected or unforeseen issues will not arise.

Furthermore, pricing and reimbursement of pharmaceutical products is subject to intense political scrutiny and the reimbursement understandings that we currently have now may be modified or rendered obsolete by the time the FPC pipeline product candidate could potentially receive regulatory approval. Such modifications could change the commercial viability of marketing the FPC pipeline product candidate which would have an effect upon the value of our drug product portfolio.

There is also a risk our FPC pipeline product candidates, even if successfully developed, approved and reimbursed, will not be acceptable to or adopted by the market. Factors that may impact market adoption may include competition, health economic value of FPC versus alternative therapeutic approaches, usability, or suitability of the product for providers.

RISKS RELATED TO CLINICAL TRIALS

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results.

Future FPC pipeline product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities before obtaining marketing approval from these regulatory authorities. The drug development and approval process is lengthy and expensive, and approval is never certain. Investigational new drugs may not prove to be safe and effective in clinical trials. We have no direct experience as a company in conducting later stage clinical trials required to obtain regulatory approval in the disease states in which we are currently investigating FPC pipeline product candidates. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. We may experience delays in clinical trials due to FDA requirements or otherwise, and may face administrative challenges or limitations when conducting clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Even if a current clinical trial is successful, participants may experience undesirable side effects or the candidate may demonstrate a lack of efficacy, so that the clinical trial may be insufficient to demonstrate that our product candidates are safe or effective for registration purposes.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of FPC pipeline product candidates may not be predictive of the results of later-stage clinical studies or trials and the results of studies or trials in one set of patients or line of treatment may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical studies and earlier stage clinical trials. In addition, data obtained from preclinical and clinical activities is subject to varying interpretations, which may delay, limit or prevent regulatory approval. It is impossible to predict when or if our future product candidates will prove effective or safe in humans in the disease states that we will be conducting the clinical trials or that they will receive regulatory approval. FPC pipeline product candidates may not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. The number of patients exposed to product candidates and the average exposure

time in the clinical development programs may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. If we are unable to successfully demonstrate the safety and efficacy of FPC pipeline product candidates in these disease states and are unable to receive the necessary regulatory approvals, our drug product portfolio could be harmed.

RISKS RELATED TO LEGAL AND REGULATORY

Our drug and concentrate businesses are business is highly regulated, resulting in additional expense and risk of noncompliance that can materially and adversely affect our business, results of operations, financial position and cash flows.

Our businesses are business is highly regulated. The testing, manufacture, sale and delivery of the products we manufacture directly or through third party CMOs are subject to extensive regulation by the FDA and by other federal, state and foreign authorities, including, with respect to our transportation operations, the U.S. Department of Transportation. Before drug product candidates or medical devices, such as our concentrate products, can be commercially marketed in the United States, the FDA must give either premarket approval or 510(k) clearance. After a product is approved, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or requirements for potentially costly post-marketing studies. In addition, manufacturers and their facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current cGMP and applicable state laws. As such, we and our CMOs are subject to continual review and periodic inspections to assess compliance with cGMP and state laws. For example, in 2023, the FDA conducted a routine GMP inspection of one of our manufacturing facilities and issued Form FDA-483 report with four observations, for which the inspector classified Voluntary Action Indicated. one observation. The Company submitted a voluntary performed corrective action plan, to which actions and resolved the FDA replied. issue. While none of the findings were finding was not serious, management time and effort will be necessary was expended for the correction and the FDA response. correction. Accordingly, we and our partners must continue to expend time, money and effort in all areas to achieve and maintain regulatory compliance. We are also required to report certain adverse reactions and production problems, if any, to applicable regulatory authorities and to comply with requirements concerning advertising and promotion for our drug products or product candidates. authorities.

If non-compliant inventory is sold or if a regulatory agency determines that we are not compliant with any applicable regulatory requirements, we may be subject to warnings from, or enforcement action by, state and federal government authorities, which may include penalties, fines, injunctions, recall or seizure of products, suspension of production, denial of future regulatory approvals, withdrawal or suspension of existing regulatory approvals, operating restrictions, injunctions and criminal prosecution. If regulatory sanctions are applied, the value of our Company and our operating results could be materially and adversely affected. For example, such actions could cause our customers to doubt the safety or efficacy of our products, which could adversely impact our business. Even a voluntary Class III recall, which is a recall of products for a defect that is unlikely to result in adverse health consequences, can have an adverse impact on the Company due to the costs of the recall or the reactions of customers. We recently conducted a Class III recall in our concentrates business due to the degradation of secondary seals on some of our bottles of concentrates, which consumed management time and effort. Further, in our discussions with the FDA, the FDA has indicated that it believes our recall, though completed, should be recharacterized as a Class II recall. Our business could also be adversely affected by delays in obtaining necessary regulatory approvals and any restrictions placed by the FDA on our intended marketing or the use of our drug product candidates.

Our failure to comply with applicable regulations could also result in product liability litigation against us. In addition, our failure to comply with applicable regulations with respect to our concentrate concentrates products could constitute a breach of our Products Purchase Agreement, providing DaVita with various remedies that would be material and adverse to us. Moreover, changes in applicable regulatory requirements could significantly increase the costs of our operations, which if such higher costs result in cost increases that we cannot recoup or that price increases exceed the thresholds specified in the Products Purchase Agreement, could give DaVita the right to terminate.

Our product candidates and drugproducts may have undesirable side effects and our product liability insurance may not be sufficient able to protect us from material liability or harm to recover under our business.

If concerns are raised regarding the safety of a product candidate as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the product candidate at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. Following FDA approval, if we or others later identify previously unknown undesirable side effects caused by our product candidate or concentrate products, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for such products or any products perceived to be similar to such products, the FDA or other applicable regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or contraindications, may suspend or withdraw their approval of the product, may require it to be removed from the market or may impose restrictions on the distribution or use of the product. Such side effects may also result in litigation against us by private litigants.

We maintain product liability insurance. We cannot be sure that such insurance would be sufficient to protect us against liabilities associated with any of these events in view of our expanding business or that such insurance will remain available at economical levels. We may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by such sanctions or product liability litigation and that could harm our business reputation and marketing ability. Any such sanctions or litigation could also hurt our ability to retain product liability insurance or make such insurance more expensive. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

We could be found to be infringing intellectual property rights of third parties, which could prevent us from selling products and could require us to pay significant damages and compel us to defend against litigation. We may be subject to claims that our employees or directors have wrongfully used or disclosed alleged trade secrets of their former employers.

It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a third party believes that one of our drug products or product candidates infringes on the third party's patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from manufacturing and selling products, forced to pay damages, compelled to license technology from the party claiming infringement and lose the opportunity to license our technology to others and collect royalty payments, any of which could have a material adverse effect on our business. If we are prevented from selling any of our concentrate or ancillary products due to a patent infringement or if our ability to sell any of our concentrate or ancillary products due to a patent infringement is materially and adversely affected, DaVita may be entitled to terminate our Products Purchase Agreement.

As is common in the medical device, biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our drug products and product candidates. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. As such, the Company advises consultants not to disclose, or use trade secrets, or proprietary information of their former employers or their former or current customers. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and day-to-day business operations.

Many of our employees and certain of our directors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and directors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. fixed price contracts.

Our business operations may subject us to numerous commercial disputes, claims, lawsuits and/or investigations.

Operating in the medical device and pharmaceutical industries involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of disputes, claims, lawsuits and investigations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. A counterparty may assert claims that we do not believe are meritorious, but we nonetheless need to defend. In addition, any commercial dispute, claim, lawsuit or investigation may divert our management's attention away from our business, we may incur significant expenses in addressing or defending any commercial dispute, claim or lawsuit or responding to any investigation, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.

We may become the target of litigation, which is costly and time-consuming to defend.

We have in the past been subject to litigation and it is possible that legal proceedings could be brought against us in the future based upon decisions we make regarding our strategy or otherwise. Litigation can be costly and time-consuming, and the results of complex legal proceedings are difficult to predict. These lawsuits assert types of claims that, if resolved against us, could give rise to substantial damages, and an unfavorable outcome or settlement of these lawsuits, or any future lawsuits, could have a material adverse effect on our business, financial condition, results of operations and/or stock price. Even if any future lawsuits are not resolved against us, the costs of defending such lawsuits may be material to our business and our operations. Moreover, these lawsuits may divert our Board and our management's attention from the operation of our business.

Our products may have or have had undesirable side effects, and our product liability insurance may not be sufficient to protect us from material liability or harm to our business.

We sell hemodialysis concentrates that are used in dialysis procedures in the United States and foreign countries. In addition, prior to its discontinuation, we marketed and sold Triferic in the United States for four years and prior to that, engaged in clinical trials to support the submission of the NDA for approval. Our international partners continue to market and sell Triferic in foreign countries. If patients experience side effects from the use of our hemodialysis concentrates or from Triferic and the statutes of limitation and repose have not expired, such side effects may result in litigation against us by private litigants.

Although we maintain product liability insurance, we cannot be sure that such insurance would be sufficient to protect us against liabilities associated with any of these events in view of our expanding business or otherwise, or that such insurance will remain available at economical levels. We may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by such sanctions or product liability litigation and that could harm our business reputation and marketing ability. Any such sanctions or litigation could also hurt our ability to retain product liability insurance or make such insurance more expensive. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

We could be found to be infringing intellectual property rights of third parties, which could prevent us from selling products and could require us to pay significant damages and compel us to defend against litigation. We may be subject to claims that our employees or directors have wrongfully used or disclosed alleged trade secrets of their former employers.

It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a third party believes that one of our products infringes on the third party's patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from manufacturing and selling products, forced to pay damages, compelled to license technology from the party claiming infringement and lose the opportunity to license our technology to others and collect royalty payments, any of which could have a material adverse effect on our business. If we are prevented from selling any of our concentrate or ancillary products due to a patent infringement or if our ability to sell any of our concentrate or ancillary products due to a patent infringement is materially and adversely affected, DaVita may be entitled to terminate our Products Purchase Agreement.

As is common in the medical device, biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our products. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. As such, the Company advises consultants not to disclose, or use trade secrets, or proprietary information of their former employers or their former or current customers. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and day-to-day business operations.

Many of our employees and certain of our directors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and directors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our business could be impacted as a result of actions by activist stockholders, including as a result of a potential proxy contest for the election of directors at our annual meeting.

The Company was We were subjected to a proxy contest at the our 2017 Annual Meeting of Stockholders, which resulted in the negotiation of changes to the Board and the incurrence of substantial costs. A future proxy contest would require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and the Board. The potential of a proxy contest could interfere with our ability to execute our strategic plan, give rise to perceived uncertainties as to our future direction, adversely affect our relationships with customers, suppliers, investors, prospective and current team members and others, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results.

We may also be subject, from time to time, to other legal and business challenges in the operation of our company due to actions instituted by activist stockholders. Responding to such actions, which may include publicity campaigns and, potentially, litigation, could be costly and time-consuming, divert the time and attention of our Board and management from our business, interfere with our ability to execute our strategic plan, give rise to perceived uncertainties as to our future direction, adversely impact our lobbying efforts, adversely affect our relationships with customers, suppliers, prospective and current team members and others, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. We cannot predict, and no assurances can be given as to, the outcome or timing of any matters relating to actions by activist stockholders or the ultimate impact on our business, results of operations, financial position and cash flows.

RISKS RELATED TO OUR COMMON STOCK

The market price of our common stock has fluctuated in the past, and is likely to continue to be volatile, which could subject us to litigation.

The market price of our common stock has fluctuated and is likely to be subject to further wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this “Risk Factors” section and others including:

- the reporting of sales, operating results and cash resources;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- changes in the structure of healthcare payment systems;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- issues in manufacturing our device products or product candidates; products;
- the results of any future clinical trials of our product candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others; and
- the introduction of technological innovations or new therapies that compete with our products or product candidates. products.

In addition, third parties may engage in trading strategies that result in intentional volatility to and control over our stock price. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company’s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Shares eligible for future sale may affect the market price of our common stock.

Any future sales by us of substantial amounts of our common stock, or the possibility of such sales, could adversely affect the market price of our common stock and also impair our ability to raise capital through an offering of our equity securities in the future. In the future, we may issue additional shares or warrants in connection with investments or for other purposes considered advisable by our Board of Directors. Board. Any substantial sale of our common stock may have an adverse effect on the market price of our common stock and may dilute the economic value and voting rights of existing stockholders.

In addition, as of December 31, 2022 December 31, 2023, there were 243,088 361,531 shares issuable upon the exercise of then-outstanding and exercisable stock options, 963,817 967,090 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable, and 16,200,990 3,793,000 shares issuable upon the exercise of then-outstanding and exercisable warrants. The market price of the common stock may be depressed by the potential exercise of these options. options and warrants and the sale of the underlying common stock. The holders of these options and warrants are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than those provided by the options. options and warrants.

We may fail to qualify for continued listing on Nasdaq, which could make it more difficult for our stockholders to sell their shares.

We are required to satisfy the continued listing requirements of Nasdaq to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of $1.00 per share. On June 11, 2021, In 2021, we received a notice from Nasdaq that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5450(a)(1) for continued listing on The Nasdaq Global Market and were unable to regain compliance in the time allotted by Nasdaq. As a result, we moved our listing to The Nasdaq Capital Market and effected an 11-for-1 reverse stock split in May 2022 to regain compliance. While we have been in compliance with the minimum closing bid price requirement since that time, there can be no assurance that we will be able to maintain compliance with the minimum bid price requirement going forward.

If our common stock were delisted by Nasdaq, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity with respect to our common stock;
- a determination that our shares are “penny stock,” which will require brokers trading in our shares to adhere to more stringent shares, and which may limit demand for our common stock among certain investors;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Our ability to use our net operating loss carryforwards to offset potential taxable income and related income taxes that would otherwise be due may be limited.

We have substantial net operating loss carryforwards ("NOLs") available to reduce future taxable income. Our ability to use our NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs. In addition to uncertainty regarding our future profitability, our use of the NOLs may be subject to annual limitations under the “ownership change” provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which may result in the expiration of some or all of the NOLs before they can be used. In general, an “ownership change” occurs if, during a rolling three-year period, there is a greater than 50% change in the percentage ownership of the corporation by 5% owners (and persons treated as 5% owners), as defined in Section 382 and related regulations. We may experience an ownership change in the future as a result of future changes in our stock ownership. The inability to use our NOLs to reduce federal taxable income could result in increased future tax liability to us and reduce the cash that would otherwise be available to our business.

We do not anticipate paying dividends in the foreseeable future.

Since inception, we have not paid any cash dividend on our common stock and do not anticipate paying such dividends in the foreseeable future. The payment of dividends is within the discretion of our Board of Directors and depends upon our earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. We intend to retain earnings and any cash resources to finance our operations. Therefore, it is highly unlikely we will pay cash dividends.

If securities analysts do not publish research or reports about our business, or if they publish negative evaluations, the price of our common stock could decline.

The trading market for our common stock may be impacted by the availability or lack of research and reports that third-party industry or financial analysts publish about the Company. us. There are many large, publicly traded companies active in the medical device and biopharmaceutical industry, which may mean it will be less likely that we receive widespread analyst coverage.

Furthermore, if one or more of the analysts who do cover the Company us downgrade our stock, our stock price would likely decline. If we do not receive adequate coverage by reputable analysts that have an understanding of our business and industry, we could fail to achieve visibility in the market, which in turn could cause our stock price to decline.

GENERAL RISK FACTORS

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine and the Middle East, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine has and the conflict in the Middle East have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions and the occurrence of natural disasters and public health crises, including delays or difficulties in manufacturing sufficient quantities of materials. If we fail to maintain inventory or deliver product as a result of such delays or difficulties, we could breach the requirement in our Products Purchase Agreement with DaVita to maintain safety stock and maintain transportation and other services, which would allow DaVita to

exercise various remedies under such agreement. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Our certificate of incorporation, bylaws and Delaware law could prevent a third party from acquiring us (even if an acquisition would benefit our stockholders), may limit the ability of our stockholders to replace our management and limit the price that investors might be willing to pay for shares of our common stock.

Our certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. These provisions could delay or prevent a change in control of the company and could limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions, among other things:

- establish a staggered board of directors Board divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- authorize our board of directors Board to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- disallow our stockholders to fill vacancies on our board of directors; board;
- establish advance notice requirements for nominations for election to our board of directors Board or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors Board to establish the number of directors between three and fifteen;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than a majority of all outstanding shares of our voting stock;
- require the approval of not less than a majority of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and
- limit the jurisdictions in which certain stockholder litigation may be brought.

We are not subject to the provisions of Section 203 of the Delaware General Corporation Law, which could negatively affect your investment.

We elected in our certificate of incorporation to not be subject to the provisions of Section 203 of the Delaware General Corporation Law ("Section 203"). In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15% or more of the corporation's voting stock. This may make us more vulnerable to takeovers that are completed without the approval of our Board of Directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court or a federal court located within the State of Delaware) is the exclusive forum for any claims that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any have exclusive jurisdiction. This choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

We believe we maintain an information technology and security program appropriate for a company our size, taking into account our operations and risks. The Company recognizes the critical importance of maintaining the trust and confidence of our investors, employees, customers and vendors. The Company's cybersecurity policies and processes are integrated into the Company's enterprise risk management program and are informed by recognized frameworks established by the National Institute of Standards and Technology, and other applicable industry standards.

In the ordinary course of our business, we collect, use, store, and transmit digitally confidential, sensitive, proprietary, and personal information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by an outside information technology vendor in cooperation with our information technology consultant, under the supervision of our Chief Corporate Affairs Officer, and include mechanisms, controls, technologies, systems, and other

processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable and secure information technology environment. For example, we conduct ongoing monitoring of critical systems for any compromised or potentially compromised accounts. We conduct regular trainings on cyber and information security, along with phishing simulations, among other topics. We conduct security audits and ongoing risk assessments, including due diligence on our key technology vendors, and other contractors and suppliers. In addition, we consult with our outside information technology vendor and our information technology consultant on a regular basis to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment.

Our Chief Corporate Affairs Officer, who reports directly to the Chief Executive Officer, and our IT Consultant, who has three decades of experience managing and leading cybersecurity oversight, together with our other executive officers, are responsible for assessing and managing cybersecurity risks. The Company's executive officers each hold undergraduate and graduate degrees in their respective fields and have extensive experiencing managing risks at the Company and at similar companies, including risks arising from cybersecurity threats. In the last fiscal year, we have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. If we were to experience a material cybersecurity incident in the future, such incidents are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information regarding cybersecurity risks that we face and potential impacts on our business related thereto, see the risk factor titled, "Our business and operations would suffer in the event of a security breach, system failure, invasion, corruption, destruction or interruption of our or our business partners' critical information technology systems or infrastructure."

The Company's Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is composed solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee and the Board receive updates on cybersecurity and information technology matters and related risk exposures from our Chief Corporate Affairs Officer, as well as our other executive officers. The Board also receives updates from the Company's management on cybersecurity risks on at least an annual basis.

Item 2. Properties.

We lease a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2024. We also lease two other manufacturing facilities, a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2025, and a 57,000 square foot facility in Greer, South Carolina under a lease expiring in February 2026. In addition, Rockwell occupied 4,100 square feet of office space in Hackensack, New Jersey expiring on October 31, 2024. This lease is currently under a sublease expiring on October 31, 2024.

We use each of our facilities to manufacture and warehouse our products. All such facilities and their contents are covered under various insurance policies which management believes provide adequate coverage. We use the office space in Wixom, Michigan as our principal administrative office. We believe that our existing leased properties are adequate and suitable for the conduct of our business and that our capital resources are sufficient to purchase, lease or construct any additional facilities required to meet our expected long-term growth needs. We expect that we may need additional manufacturing capacity and distribution facilities to meet our business requirements. requirements and anticipate they will be available on commercially available terms.

Item 3. Legal Proceedings.

We may be involved in certain routine legal proceedings from time to time before various courts and governmental agencies. We cannot predict the final disposition of such proceedings. We regularly review legal matters and record provisions for claims considered probable of loss. The resolution of these pending proceedings is not expected to have a material effect on our operations or consolidated financial statements in the period in which they are resolved. Information pertaining to legal proceedings is provided under the heading "Litigation" in Note 15, Commitments and Contingencies, to the consolidated financial statements and is incorporated by reference herein.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed on The Nasdaq Capital Market under the trading symbol "RMTI".

Holders

As of February 28, 2023 February 29, 2024, there were were 37 holders of record of our common stock.

Dividend Policy

Our Board of Directors has discretion whether or not to pay dividends. Among the factors our Board of Directors considers when determining whether or not to pay dividends are our earnings, capital requirements, financial condition, future business prospects and business conditions. We have never paid any cash dividends on our common stock and do not anticipate paying dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our operations.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

Rockwell Medical is a healthcare company that develops, manufactures, commercializes, and distributes a portfolio of hemodialysis products for dialysis providers worldwide.

Rockwell is a revenue-generating business and the second largest supplier of liquid and powder acid and bicarbonate concentrates for dialysis patients in the United States.Hemodialysis is the most common form of end-stage kidney disease treatment and is usually typically performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient's home. This represents a large market opportunity for which we believe Rockwell's products are well-positioned to meet the needs of patients.

Rockwell manufactures provides the hemodialysis concentrates under Current community with products controlled by a Quality Management System regulated by the U.S. Food and Drug Administration ("FDA"). Rockwell is ISO 13485 Certified and adheres to current Good Manufacturing Practices ("cGMP") regulations and Association for Advancement of Medical Instrumentation ("AAMI") standards. Rockwell manufactures hemodialysis concentrates at its three facilities in Michigan, Texas, South Carolina, and South Carolina Texas totaling approximately 175,000 square feet, and manufactures its dry acid concentrate mixers at its facility in Iowa. In addition, the Company manufactures the former Evoqua product line in Minnesota under a contract manufacturing agreement with a contract manufacturing organization. (See Note 4 of the accompanying consolidated financial statements for further detail). On February 12, 2024, the Company entered into an amendment to its contract manufacturing agreement to extend the term to December 31, 2024. The Company plans to transfer the manufacturing of the former Evoqua product line to one of its own manufacturing facilities by the end of 2024, which the Company believes will reduce production costs for these products. Rockwell delivers the majority of its hemodialysis concentrates products and mixers to dialysis clinics throughout the United States and internationally utilizing its own delivery trucks and third-party carriers. Rockwell has developed a core expertise in manufacturing and delivering hemodialysis concentrates, and has built a longstanding reputation for reliability, quality, and excellent customer service.

On July 10, 2023, the Company executed and consummated the transactions contemplated by the Evoqua Acquisition. Subject to the terms and conditions of the Purchase Agreement, at the Closing, the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to manufacturing and selling of hemodialysis concentrates products, all of which are manufactured under a contract manufacturing agreement with a third-party organization. Total consideration was $17.4 million, comprising a cash payment at Closing of $12.4 million (inclusive of transaction costs) and two $2.5 million

In addition deferred payments, the first to its primary focus be paid on hemodialysis concentrates, the first anniversary and the second to be paid on the second anniversary of the Closing. See Note 4 for further detail.

On August 7, 2023, Rockwell also has was informed by Wanbang, the Company's commercialization partner in China for Triferic, that the main efficacy results of Wanbang's clinical trial for Triferic (dialysate) compared with placebo were not obtained and Wanbang will not will not bring the product forward to registration. As a proprietary parenteral iron product, Triferic (ferric pyrophosphate citrate, result, the remaining $2.1 million of deferred license revenue was recorded into revenue, and the related portion of long-term inventory of $1.1 million was reserved for.

On September 18, 2023, Rockwell and our long-time partner, DaVita, Inc. ("FPC" DaVita"), a leading provider of kidney care, entered into an Amended and Restated Products Purchase Agreement (the "Amended Agreement"), which amends and restates the Product Purchase Agreement, dated July 1, 2019, as amended, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amended Agreement, the Company and DaVita agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment to Rockwell on or after December 1, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, to further extend the term through December 31, 2025. In the event of such an extension, product pricing will be increased for the extended term. In addition, DaVita is indicated required to maintain hemoglobin in adult patients provide the Company with hemodialysis-dependent chronic kidney disease. While nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for the amount forecasted, purchase additional product, or the Company may terminate the Amended Agreement. Upon expiration or termination of the Amended Agreement, and upon request by DaVita, the Company has agreed to provide transition services to DaVita during a transition period.

Additionally, during the year ended December 31, 2023, Rockwell has discontinued commercialization of Triferic entered into several long-term product purchase agreements, which include supply and purchasing commitments from certain parties. These agreements include the largest non-profit dialysis provider in the United States, States; Concerto Renal Services, the Company has established several international partnerships with companies seeking to develop and commercialize Triferic outside largest provider of dialysis in skilled nursing facilities in the United States States; Sanderling Renal Services, Inc., a full-service provider of in-center, home dialysis and renal telemedicine services focusing on patients in rural and underserved communities across the United States; Centers for Dialysis Care, the largest non-profit, independent outpatient dialysis provider in Northeast Ohio; Houston Methodist, a leading health system and academic medical center; Dialyze Direct, a leading provider of home dialysis services in the skilled nursing facility setting; and Outset Medical (Nasdaq:OM), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis with its Tablo®

Hemodialysis System, which is working closely with these international partners FDA-cleared for use from the hospital to develop and commercialize Triferic in their respective regions. Additionally, Rockwell continues to evaluate the viability of its FPC platform and FPC's potential to treat iron deficiency, iron deficiency anemia, and acute heart failure.

Reverse Stock Split home.

On May 9, 2022 January 2, 2024, the Company's stockholders authorized Loan Agreement was amended to include, among other things, an interest-only period for 30 months, or up to 36 months if certain conditions are met, and extend the Company's Board of Directors maturity date to effect a reverse stock split of all outstanding shares of common stock, warrants and options. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one-for-eleven shares, which became effective on May 13, 2022 January 1, 2029. The Company's outstanding stock options were also adjusted to reflect the one-for-eleven reverse stock split of the Company's common stock. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The reverse stock split resulted in an adjustment to the Series X convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. All share and per share data in these condensed consolidated financial statements and related notes hereto have been retroactively adjusted to the account (See Note 19 for the effect of the reverse stock split for the periods ended December 31, 2022 and 2021, respectively. further detail).

Results of Operations

The following table summarizes our operating results for the periods presented below (dollars in thousands):

	For the Year Ended December 31,				
	2022	% of Revenue	2021	% of Revenue	% Change
Net Sales	$ 72,810		$ 61,931		17.6 %
Cost of Sales	68,733	94.4 %	64,351	103.9 %	6.8
Gross (Loss) Profit	4,077	5.6	(2,420)	(3.9)	(268.5)
Research and Product Development	3,119	4.3	6,835	11.0	(54.4)
Selling and Marketing	2,094	2.9	5,733	9.3	(63.5)
General and Administrative	15,644	21.5	15,348	24.8	1.9
Operating Loss	**$(16,780)**	**(23.0)%**	**$(30,336)**	**(49.0)%**	**(44.7)%**

	For the Year Ended December 31,				
	2023	% of Revenue	2022	% of Revenue	% Change
Net Sales	$83,612	$	$72,810		
Cost of Sales	74,908	89.6	89.6 %	68,733	94.4
Gross Profit	8,704	10.4 %	4,077	5.6	%
Research and Product Development	1,107	1.3	1.3 %	3,119	4.3
Selling and Marketing	2,125	2.5	2.5 %	2,094	2.9
General and Administrative	12,142	14.5	14.5 %	15,644	21.5
Operating Loss	**$ (6,670)**		**(8.0) %**	**$ (16,780)**	**(23.0) %**

Net Sales

During the year ended December 31, 2022 December 31, 2023, our net sales were $72.8 million $83.6 million compared to net sales of $61.9 million $72.8 million during the year ended December 31, 2021 December 31, 2022. Net sales of hemodialysis concentrates to dialysis providers and distributors in the

United States and abroad were $71.7 million $81.3 million for the year ended December 31, 2022 December 31, 2023 compared to $60.8 million $71.7 million for the year ended December 31, 2021 December 31, 2022. Net sales of Triferic (dialysate) were $1.2 million $2.3 million and $1.1 million $1.2 million for the years ended December 31, 2022December 31, 2023 and 2021, 2022, respectively. The increase in net sales of $10.9 million Triferic (dialysate) was due to Wanbang's decision to not bring the product forward to registration. The increase of $10.8 million in net sales is primarily related due to the amendment restructuring of our supply products purchase agreement with DaVita, the reacquired rights to commercialize and distribute our products, the asset acquisition of Evoqua, onboarding of new customers and increased pricing to other customers. During 2022, the Company made a strategic decision to discontinue its NDAs for Triferic and Triferic AVNU in the United States.

Cost of Sales and Gross Profit

Cost of sales during the year ended December 31, 2022 December 31, 2023 was $68.7 million $74.9 million, resulting in gross profit of $4.1 million $8.7 million, compared to cost of sales of $64.4 million $68.7 million and a gross loss profit of $2.4 million $4.1 million during the year ended December 31, 2021 December 31, 2022. Gross profit increased by $6.4 million $4.6 million during the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022 primarily due to price increases for all business during the year including the amended products purchase agreement restructuring of our supply contract with DaVita offset by volume reductions in 2022, lower distribution costs, onboarding of new customers, increased pricing to other customers and increased distribution costs. net impact of recording the remaining deferred license revenue associated with Wanbang and the associated inventory reserve as described above.

Research and Product Development Expense

Research and product development expenses were $3.1 million $1.1 million for the year ended December 31, 2022 December 31, 2023 compared with $6.8 million $3.1 million during the year ended December 31, 2021 December 31, 2022. The decrease of $3.7 million $2.0 million is related due to headcount reductions a reduction in wages and project costs resulting from the decision to put pause all research related to our FPC for Home Infusion program on hold due to program. Approximately 37% of research and development expenses for the significant capital expenditure and resources to support additional re-formulation work and conduct a Phase 2 study. year ended December 31, 2023 were comprised of severance costs.

Selling and Marketing Expense

Selling and marketing expenses were $2.1 million during the year ended December 31, 2022 December 31, 2023 compared with $5.7 million $2.1 million during the year ended December 31, 2021 December 31, 2022. The decrease of $3.6 million is due We continue to a decrease in evaluate marketing spend and focus on target opportunities for our Triferic products and a headcount reduction.greater return on investments.

General and Administrative Expense

General and administrative expenses were $12.1 million during the year ended December 31, 2023 compared with $15.6 million during the year ended December 31, 2022 compared with $15.3 million during the year ended December 31, 2021. The $0.3 million increase $3.5 million decrease was driven primarily by increases a reduction in executive severance expenses wages and incentive compensation of $1.4 million $0.9 million, legal costs of $0.2 million and travel expense $0.9 million, insurance costs of $0.1 million, offset by decreases in employee incentives of $0.6 million, various cost cutting measures of $0.5 million $0.9 million, and FDA fees relating to approved products of $0.2 million $0.9 million.

Other Income (Expense) Expense

Other income consisted of interest income of $33,000 and $22,000 Total other expense for the years ended December 31, 2022 December 31, 2023 and and December 31, 2022 December 31, 2021, respectively. Other expense consisted of was $1.8 million and $1.9 million, respectively, which was primarily related to interest expense related to incurred on our debt facility (see of $2.3 million and $1.9 millionfor the years ended December 31, 2023 and December 31, 2022, respectively. See Note 1617 to the consolidated financial statements for more information on our debt facility) totaling $1.9 million and $2.4 million for the years ended December 31, 2022 and December 31, 2021, respectively. facility.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and have funded our operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. At December 31, 2022 December 31, 2023, we had an accumulated deficit of approximately $388.8 million $397.2 million and shareholders' stockholders' equity of $14.1 million $21.3 million. As of December 31, 2022 December 31, 2023, we had approximately $21.5 million $10.9 million of cash, cash equivalents and investments available-for-sale, and working capital of $17.6 million $12.1 million. Net cash used in operating activities for the year ended December 31, 2022 December 31, 2023 was approximately $17.4 million $9.4 million. These factors raised substantial doubt about

On July 10, 2023, Armistice Capital Master Fund Ltd. (“Armistice”) exercised its warrant to purchase 9,900,990 shares of common stock with an exercise price of $1.39 per share (the "Prior Warrant") and the Company’s ability Company received gross proceeds of approximately $13.8 million (See Note 12 to continue as the consolidated financial statements included elsewhere in this Form 10-K).

On July 10, 2023, the Company completed the Evoqua Acquisition. Total consideration was $17.4 million, comprising a going concern cash payment at Closing of $12.4 million (inclusive of transaction costs) and depended, in part, two $2.5 million deferred payments, the first to be paid on the degree first anniversary and the second to be paid on the second anniversary of success in addressing inflationary pressures affecting the Company’s concentrates business, as well as Closing. See Note 4 to the Company’s ability to contain costs, raise additional working capital, if needed, and remain in compliance with consolidated financial and reporting covenants under the Company’s secured loan.

statements for further detail.

During the year ended December 31, 2022 December 31, 2023, the Company continued to experience significant inflationary pressures in its dialysis concentrates business, which has resulted in operating losses associated with this business line. As a result of these inflationary pressures, and in light of the fact that the Company's concentrates

business operated at a loss in 2021, 2022, the Company sought to renegotiate certain terms of its supply contracts with the Company's two largest customers in an effort to allow the Company to stabilize its concentrates business.

On April 6, 2022, the Company and DaVita entered into an amendment (the "Amendment") to the Products Purchase Agreement, dated July 1, 2019, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amendment, the Company and DaVita agreed to certain price increases, effective May 1, 2022, as well as the pass-through of certain inflationary costs, determined on a quarterly basis. The Amendment also requires the Company to implement certain cost containment and cost-cutting measures. The Amendment contains certain covenants with respect to the Company's ongoing operations, including a minimum cash covenant of $10 million, or the Company will be in default under the Products Purchase Agreement. An event of default could result in termination of that agreement.

On April 6, 2022, the Company and DaVita entered into the SPA, pursuant to which the Company issued $15 million of preferred stock to DaVita in two separate tranches. The Company initially issued 7,500 shares of a newly designated series of preferred stock, which is designated "Series X Convertible Preferred Stock" (the "Series X Preferred Stock") for gross proceeds of $7.5 million. On June 15, 2022, the Company issued to DaVita an additional 7,500 shares of Series X Preferred Stock in a second closing (the "Second Tranche") for an additional $7.5 million. The Second Tranche was conditioned upon the Company raising an additional $15.0 million in capital within a certain timeline, which took place on June 2, 2022.

On April 8, 2022, the Company entered into a sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time up to $12,200,000 of shares of Company's common stock through the Agent. During the quarter ended December 31, 2022, no sales were made pursuant to the Sales Agreement. Subject to restrictions under General Instruction I.B.6 to Form S-3, approximately $12.2 million remains available for sale under the ATM facility.

On May 30, 2022, the Company entered into a Securities Purchase Agreement (the "RD Purchase Agreement") with the purchaser named therein (the "Purchaser"), pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Offering"), 844,613 shares of its common stock at price of $1.39 per share, and prefunded warrants to purchase up to an aggregate of 7,788,480 shares of common stock (the "Pre-Funded Warrants" and the shares of common stock underlying the Pre-Funded Warrants, the "Warrant Shares"). The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each Pre-Funded Warrant is $0.0001 per share.

Also on May 30, 2022, concurrently with the Offering, the Company entered into a Securities Purchase Agreement with the Purchaser (the "PIPE Purchase Agreement") relating to the offering and sale (the "Private Placement") of warrants to purchase up to a total of 9,900,990 shares of common stock and pre-funded warrants to purchase up to a total of 1,267,897 shares of common stock (the "PIPE Warrants"). Each warrant was sold at a price of $0.125 per underlying warrant share and is exercisable at an exercise price of $1.39 per share. The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each prefunded warrant is $0.0001 per share. The Offering and the Private Placement closed on June 2, 2022. The net proceeds to the Company from the Offering and the Private Placement were approximately $14.9 million, after deducting fees and expenses.

On November 10, 2022, the Company entered into a Second Amendment to the Loan and Security Agreement (the "Second Amendment") dated as of November 14, 2022 with Innovatus, which amended the Loan Agreement. Pursuant to the Second Amendment, the Company (i) prepaid an aggregate principal amount of $5.0 million in Term Loans (as defined in the Loan Agreement) in one installment on November 14, 2022; (ii) shall pay interest only payments until September 2023 at which time will resume scheduled debt payments (see Note 16 to the consolidated financial statements included elsewhere in this Form 10-K for more information on our debt facility).

Management evaluated it's going concern by reviewing the Company's operational plans which include executing on the projected financial information including price increases, acquisition of new customers, projected growth of margins and cost containment activities. Additionally, the Company's operational plans also include raising capital, if needed, by using our ATM facility or other methods or forms of financings, subject to existing limitations. Based on the currently available working capital, expectation of the ability of management to execute on the Company's operational plans noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report. Accordingly, management believes that the factors noted above which raised substantial doubt about the Company's ability to continue as a going concern have been alleviated.

The Company may require additional capital to sustain its operations and make the investments it needs to execute its strategic plan. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume such financing will be available on favorable terms, if at all.

In addition, the Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of December 31, 2022, the Company is in compliance with all financial covenants (See Note 16 to the consolidated financial statements included elsewhere in this Form 10-K for more information on our debt facility).

Global Economic Considerations

The COVID-19 pandemic and resulting domestic and global disruptions, particularly in the supply chain and labor market, among other areas, have adversely affected Rockwell's business and operations, including, but not limited to, the Company's sales and marketing efforts and its research and development activities, the Company's plant and transportation operations, and the operations of third parties upon whom Rockwell relies. The Company's international business development activities may also continue to be negatively impacted by COVID-19.

In addition, the global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine and other political tensions, and lingering effects of the COVID-19 pandemic. Such challenges have caused, and may continue to cause, recession fears, rising interest rates, foreign exchange volatility and inflationary pressures. At this time, we are unable to quantify the potential effects of this economic instability on our future operations.

Rockwell has utilized a range of financing methods to fund its operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding, refinancing, or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect the Company's liquidity and capital resources in the future.

General

The actual amount of cash that we will need to execute our business strategy is subject to many factors, including, but not limited to the costs associated with our manufacturing and transportation operations related to our concentrate business.

We may elect to raise capital in the future through one or more of the following: (i) equity and debt raises through the equity and capital markets, though there can be no assurance that we will be able to secure additional capital or funding on acceptable terms, or if at all; and (ii) strategic transactions, including potential alliances and collaborations focused on markets outside the United States, as well as potential combinations (including by merger or acquisition) or other corporate transactions. In addition, any debt financing is limited by the terms of our Securities Purchase Agreement with DaVita. Specifically, until DaVita owns less than 50% of its investment, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $5 million or to refinance existing debt, unless DaVita consents.

We believe our ability to fund our activities in the long term will be highly dependent upon (i) our ability to execute on the growth strategy of our hemodialysis concentrates business, (ii) our ability to achieve profitability, and (iii) our ability to identify, develop, in-license, or acquire new products in developing our renal care product portfolio. All of these strategies are subject to significant risks and uncertainties such that there can be no assurance we will be successful in achieving them. If we are unsuccessful in executing our business plan and we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

Management evaluated it's going concern by reviewing the Company's operational plans, which include executing on the projected financial information, including price increases, acquisition of new customers, projected growth of margins and cost containment activities. Based on the currently available working capital and expectation of the ability of management to execute on the Company's operational plans noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report. Additionally, the Company's plans include raising capital, if needed, by using the $11 million remaining on its ATM facility or other methods or forms of financings, subject to existing limitations.

In 2023, the Company was no longer subject to the "baby shelf" limitations under Form S-3, which limit the amount the Company may offer pursuant to its registration statement on Form S-3.

The Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of December 31, 2023, the Company is in compliance with all covenants (See Note 17 to the consolidated financial statements included elsewhere in this Form 10-K for more information on our debt facility).

Global Economic Considerations

The global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine, the Israel-Hamas conflict and other political tensions, and the occurrence of natural disasters and public health crises. Such challenges have caused, and may continue to cause, recession fears, rising interest rates, foreign exchange volatility and inflationary pressures. At this time, we are unable to quantify the potential effects of this economic instability on our future operations.

Rockwell has utilized a range of financing methods to fund its operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding, refinancing, or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect the Company's liquidity and capital resources in the future.

Cash Used in Operating Activities

Net cash used in operating activities was $17.4 million $9.4 million for the year ended December 31, 2023. The net loss for this period was less than net cash used in operating activities by $1.0 million, which was primarily attributable to increases of non-cash expenses of $6.3 million, consisting primarily of $2.0 million of changes to the right to use assets, $1.4 million of depreciation and amortization, $1.1 million of inventory reserves, $0.9 million of stock-based compensation, $1.1 million of debt financing cost amortization and accretion of discount and premium, and a $7.2 million net change in assets and liabilities.

Net cash used in operating activities was $16.9 million for the year ended December 31, 2022. The net loss for this period was higher than net cash used in operating activities by $1.3 million $1.8 million, which was primarily attributable to non-cash expenses of $3.9 million $3.9 million, consisting primarily of $2.0 million $2.0 million of amortization of the right to use assets, $0.6 million $0.6 million of depreciation and amortization, $0.6 million $0.6 million of inventory reserves, $0.4 million $0.4 million of debt financing cost amortization and accretion of discount, $0.3 million $0.3 million of stock-based compensation, and a $2.6 million $2.1 million net change in assets and liabilities.

Cash Used in Investing Activities

Net cash used in operating investing activities was $33.5 million for $3.0 million during the year ended December 31, 2021 December 31, 2023. The net loss for this period was less than net cash used in operating activities by $0.9 million, which was primarily attributable due to non-cash expenses the $12.4 million of $4.0 million, consisting primarily cash paid in connection with the Evoqua acquisition, $5.7 million in purchases of $1.8 million our available-for-sale investments and $0.3 million for the purchase of amortization equipment, offset by proceeds from the sale of the right to use assets, $0.7 million our available-for-sale investments of depreciation and amortization, $0.9 million of stock-based compensation, $0.1 million of inventory reserves, $0.4 million of debt financing cost amortization and accretion of discount, and a $4.8 million net change in assets and liabilities.

Cash Provided by (Used in) Investing Activities

$15.3 million.

Net cash used in investing activities was $2.4 million during the year ended December 31, 2022. . The net cash provided used was primarily due to the purchase of investments available-for-sale of $21.3 million$21.3 million, offset by $19.2 million$19.2 million sale of our available-for-sale investments and $0.3 million$0.3 million for the purchase of equipment.

Net cash provided by investing activities was $0.3 million during the year ended December 31, 2021. The net cash provided was primarily due to the purchase of investments available-for-sale of $26.1 million, offset by $26.9 million sale of our available-for-sale investments and $0.5 million for the purchase of equipment.

Cash (Used in) Provided by Financing Activities

Net cash provided by financing activities was $16.6 million $11.3 million during the year ended December 31, 2023. The net cash provided by financing activities was primarily due to the net proceeds from issuance of equity securities of $14.9 million, primarily comprised of gross proceeds from the issuance of common stock of $13.8 million in connection with Armistice's exercise of the Prior Warrant, offset by payments on the Company's debt, short term note payable, and financing leases which aggregated $3.5 million during the year ended December 31, 2023.

Net cash provided by financing activities was $16.2 million during the year ended December 31, 2022. The net cash provided by financing activities was primarily due to net proceeds from issuance of equity securities of $29.8 million$29.8 million offset by payments on the Company's debt and short term note payable of $13.2 million$13.2 million.

Net

Contractual Obligations and Other Commitments

We generally expect to satisfy our material cash used requirements, including contractual obligations and commitments, with cash on hand and cash provided by operating activities. See Notes 14, 15, 16, and 17 to the consolidated financial statements included elsewhere in financing activities was $2.2 million during the year ended December 31, 2021. The net cash used in financing activities was primarily due to payments on the Company's debt and short term note payable. this Form 10-K for additional disclosures.

Critical Accounting Estimates and Judgments

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. These accounting principles require us to make estimates, judgments and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and contingencies. All significant estimates, judgments and assumptions are developed based on the best information available to us at the time made and are regularly reviewed and updated when necessary. Actual results could differ from these estimates. Changes in estimates are reflected in our financial statements in the period of change based upon on-going actual experience, trends, or subsequent realization depending on the nature and predictability of the estimates and contingencies.

Interim changes in estimates are generally applied prospectively within annual periods. Certain accounting estimates, including those concerning revenue recognition, allowance for doubtful accounts, inventory reserves, share based compensation, impairments of long-lived assets, and accounting for income taxes, are considered to be critical in evaluating and understanding our financial results because they involve inherently uncertain matters and their application requires the most difficult and complex judgments and estimates. These are described below. For further information on our accounting policies, see Note 3 to our Consolidated Financial Statements. consolidated financial statements.

Fair Value Measurements

Nonrecurring Valuations. The assets acquired through the Evoqua Acquisition were recorded at relative fair value, which required the determination of the fair values of assets acquired as of the acquisition date. In making these fair value determinations, we were required to make estimates and assumptions that affected the recorded amounts, including, but not limited to, (i) for the customer relationships intangible asset, expected future cash flows, discount rates and remaining useful life and (ii) for the equipment, replacement cost. To assist us in making these fair value determinations, we engaged third-party valuation specialists. Our estimates of fair value are based upon assumptions we believe to be reasonable, but which are inherently uncertain.

Revenue Recognition

The Company recognizes revenue under Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers.* The core principle of the new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue.

Shipping and handling costs associated with outbound freight related to contracts with customers are accounted for as a fulfillment cost and are included in cost of sales when control of the goods transfers to the customer.

Deferred License Revenue - Upfront fees received under distribution and license agreements have been deferred as a contract liability. For all existing distribution and license agreements, the distribution and license agreement is not a distinct performance obligation from the underlying product sales. In instances where regulatory approval of the product has not been established and we do not have sufficient experience with the foreign regulatory body to conclude that regulatory approval is probable, the revenue for the performance obligation is recognized over the term of the license agreement (over time recognition). Conversely, when regulatory approval already exists or is probable, revenue is recognized at the point in time that the estimated product sales under the agreement occur.

Accounts Receivable

Accounts receivable are stated at invoice amounts. The carrying amount of trade accounts receivable is reduced by an allowance for doubtful accounts that reflects our best estimate of accounts that may not be collected. We review The Company reviews outstanding trade accounts receivable balances and based on our its assessment of expected collections, we estimate the Company estimates the portion, if any, of the balance that may not be collected as well as a general valuation allowance for other accounts receivable based primarily on future forecasts, historical experience. loss information, and current economic conditions. All accounts or portions thereof deemed to be uncollectible are written off to the allowance for doubtful accounts. credit losses and credit loss expense.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined on the first-in first-out (FIFO) method. Inventory that is not expected to be converted to cash over the next year is classified as non-current. Our policy is to reserve for our drug product inventory that we determine is unlikely to be sold to, or if sold, unlikely to be utilized by our customers on or before its expiration date.

Property and Equipment

Property and equipment are recorded at cost and are depreciated using the straight-line method over the useful lives of the assets, which range from three to ten years. Expenditures for routine maintenance and repairs are expensed as incurred. Leasehold improvements are amortized using the straight-line method over the shorter of the useful lives or the related lease term.

Impairment of Long-lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. Impairment losses on long-lived assets, such as real estate and equipment and definite-lived intangible assets, are recognized when events or changes in circumstances indicate that the undiscounted cash flows estimated to be generated by such assets are less than their carrying value and, accordingly, all or a portion of such carrying value may not be recoverable. Impairment losses are then measured by comparing the fair value of assets to their carrying amounts. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, there were no impairments of long-lived assets.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date. We do not amortize goodwill and intangible assets with indefinite useful lives.

We review goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit or the indefinite-lived intangible assets below their carrying values.

Intangible assets with definite lives are amortized over their estimated useful lives. Intangible assets subject to amortization are reviewed for potential impairment whenever events or circumstances indicate that carrying amounts may not be recoverable.

Definite-lived intangible assets consist of our license fees related to customer relationships intangible asset recorded in connection with the technology, intellectual property and marketing rights for Triferic covered under certain issued patents have been capitalized and are Evoqua Acquisition, which is being amortized over the life of the related patents which is generally 17 20 years.

Deferred Revenue

In October 2014, the Company entered into a 10-year Distribution Agreement with Baxter and received an upfront fee of $20 million. The upfront fee was recorded as deferred revenue and is being recognized based on the proportion of product shipments to Baxter in each period, compared with total expected sales volume over the term of the Distribution Agreement. On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. The Company recognized revenue of approximately $2.5 million and $1.9 million related to the Baxter agreement for each of the years ended December 31, 2022 and 2021, respectively.

In 2016, the Company entered into a distribution and license agreement with Wanbang (the "Wanbang Agreement") and received an upfront fee of $4.0 million. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $0.2 million for both of the years ended December 31, 2022 and 2021. Deferred revenue related to the Wanbang Agreement totaled $2.3 million and $2.5 million for the years ended December 31, 2022 and 2021, respectively.

On January 14, 2020, the Company entered into license and supply agreements with Sun Pharma (the "Sun Pharma Agreements"), for the rights to commercialize Triferic (dialysate) in India. Under the terms of the Sun PharmaAgreements, Sun Pharma will be the exclusive development and commercialization partner for Triferic (dialysate) in India, and the Company will supply the product to Sun Pharma. In consideration for the license, the Company received an upfront fee of $0.1 million, and will be eligible for milestone

payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Sun Pharma, will guide the development and execution for Triferic (dialysate) in India. Sun Pharma will be responsible for all clinical and regulatory approval, as well as commercialization activities. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $10,000 for both of the years ended December 31, 2022 and 2021. Deferred revenue related to the Sun Pharma Agreement totaled $0.1 million as of December 31, 2022 and 2021, respectively.

On September 7, 2020, the Company entered into a license and supply agreements with Jeil Pharmaceutical (the "Jeil Agreements"), for the rights to commercialize Triferic (dialysate) in South Korea. Under the terms of the Jeil Agreements, Jeil Pharmaceutical will be the exclusive development and commercialization partner for Triferic (dialysate) in South Korea, and the Company will supply the product to Jeil Pharmaceutical. In consideration for the license, the Company received an upfront fee of $0.2 million, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company andJeil Pharmaceutical, will guide the development and execution for Triferic (dialysate) in South Korea. Jeil Pharmaceutical will be responsible for all clinical and regulatory approval, as well as commercialization activities. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of $18,158 and $10,000 during the year ended December 31, 2022 and

2021, respectively. Deferred revenue related to the Jeil Agreement totaled $0.4 million and $0.2 million as of December 31, 2022 and 2021, respectively.

On June 2021, the Company entered into license and supply agreements with Drogsan Pharmaceuticals (the "Drogsan Agreements"), for the rights to commercialize Triferic (dialysate) and Triferic AVNU in Turkey. Under the terms of the Drogsan Agreements, Drogsan Pharmaceuticals will be the exclusive commercialization partner for Triferic (dialysate) and Triferic AVNU in Turkey. In consideration for the license, the Company received an upfront fee of $0.15 million, and will be eligible for milestone payment and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Drogsan Pharmaceuticals, will guide the execution for Triferic (dialysate) and Triferic AVNU in Turkey. Drogsan Pharmaceuticals will be responsible for all regulatory approval and commercialization activities, and the Company will supply the product to Drogsan Pharmaceuticals for Turkey. The upfront fee will be recorded as deferred revenue and will be recognized as revenue based on the agreement term. The Company recognized revenue of $15,000 and $7,500 during the year ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Drogsan Agreements totaled approximately $0.1 million as of December 31, 2022 and 2021 respectively.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company recorded stock-based compensation expense on its options granted under the Company's equity compensation plans to its directors and officers, and its employees.

Accounting for Income Taxes

We estimate our income tax provision to recognize our tax expense and our deferred tax liabilities and assets for future tax consequences of events that have been recognized in our financial statements using current enacted tax laws. Deferred tax assets must be assessed based upon the likelihood of recoverability from future taxable income and to the extent that recovery is not likely, a valuation allowance is established. The allowance is regularly reviewed and updated for changes in circumstances that would cause a change in judgment about whether the related deferred tax asset may be realized. These calculations and assessments involve complex estimates and judgments because the ultimate tax outcome can be uncertain and future events unpredictable. If we determine that the deferred tax asset will be realized in the future, it may result in a material beneficial effect on earnings.

New Accounting Pronouncements

New accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of

recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption. For further discussion on recent accounting pronouncements, please see Note 3, "*New Accounting Pronouncements*," to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Per §229.305 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

Item 8. Financial Statements and Supplementary Data.

The Consolidated Financial Statements consolidated financial statements of the Registrant and other information required by this item are set forth beginning on page F-1 immediately following the signature page hereof and incorporated herein by reference.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, as appropriate, to allow timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2022 December 31, 2023. Based upon that evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022 December 31, 2023. Additionally, the Company's management, including the Chief Executive Officer, has concluded that the consolidated financial statements included in this Annual Report are fairly stated, in all material respects, in accordance with generally accepting accounting principles in the United States for each of the periods presented herein.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain internal control over financial reporting designed to provide reasonable, but not absolute, assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, internal control over financial reporting determined to be effective provides only reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2022 December 31, 2023. In making their assessment of internal control over financial reporting, our management used the criteria described in the 2013 Internal Control—Integrated

Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022 December 31, 2023.

Attestation Report of the Registered Public Accounting Firm

As a non-accelerated filer, we are not required to provide an attestation report on our internal control over financial reporting issued by the Company's independent registered public accounting firm.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2022 December 31, 2023, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

(a) Appointment of Principal Accounting Officer

Effective March 20, 2024, the Company's Senior Vice President of Finance, Jesse Neri, 46, has, in addition to his current responsibilities, assumed the role of principal accounting officer. Mr. Neri will not receive any additional compensation related to this appointment.

Prior to joining the Company in October 2023, Mr. Neri was Executive Director of Finance for Hemavant Sciences from August 2022 to October 2023. Before joining Hemavant, he was Executive Director of Financial Planning and Analysis for Aruvant Sciences from August 2021 to August 2022. From July 2020 to August 2021, he provided financial consulting services to a variety of life sciences companies. Previously, he served in a variety of finance roles at Zyla Life Sciences from June 2015 to July 2020, including most recently as Senior Vice President of Finance from January 2020 to July 2020. Mr. Neri has a B.S. in Business Administration from Villanova University and an MBA from Drexel University.

Mr. Neri has no familial relationships with any executive officer or director of the Company. There have been no transactions in which the Company has participated and in which Mr. Neri had a direct or indirect material interest that would be required to be disclosed under Item 404(a) of Regulation S-K.

(b) Trading Arrangements

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the quarter ended December 31, 2023, as such terms are defined under Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to information in our proxy statement for our 2023 2024 Annual Meeting of Stockholders (the "2023 "2024 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2022 December 31, 2023, including under headings "Election of Directors," "Directors Continuing in Office," "Executive Officers," "Corporate Governance" and, as applicable, "Delinquent Section 16(a) Reports."

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, employees and officers, including our principal executive officer, our principal financial officer, principal accounting officer and persons performing similar functions. Our Code of Business Conduct and Ethics is available on our website at *www.rockwellmed.com*. To the extent required by applicable rules, future material amendments or waivers relating to the Code of Business Conduct and Ethics will be disclosed on our web site referenced in this paragraph with within four business days following the date of such amendment or waiver.

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated herein by reference to information in our 2023 2024 Proxy Statement, including under headings "Compensation of Executive Officers" and "Director Compensation."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 is incorporated herein by reference to information in our 2023 2024 Proxy Statement, including under heading "Security Ownership of Certain Beneficial Owners and Management."

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes our compensation plans, including individual compensation arrangements, under which our equity securities are authorized for issuance as of December 31, 2022 December 31, 2023:

Plan Category	Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under (excluding securities reflected in column (a))	Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under (excluding securities reflected in column (a))
		(a)					(a)	(b) (c)
		(a)	(b)	(c)				

Equity compensation plans approved by security holders (1)					
Equity compensation plans approved by security holders (1)					
Equity compensation plans approved by security holders (1)	Equity compensation plans approved by security holders (1)	788,615	$	12.29	107,335
Equity compensation plans not approved by security holders (2)	Equity compensation plans not approved by security holders (2)	544,181	$	3.50	—
Total	Total	1,332,796	$	8.32	107,335

(1) Consists of 662,724 704,417 stock options with a weighted average exercise price of $12.29, 125,000 $7.61, 258,885 restricted stock units issued at $1.47 $1.97 and 891 890 restricted stock awards issued at $62.70.

(2) Consists of 544,181 624,204 stock options with a weighted average exercise price of $3.50. $2.53.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by this Item 13 is incorporated herein by reference to information in our 2023 2024 Proxy Statement, including under headings “Independence” and “Certain Relationships and Related Party Transactions.”

Item 14. Principal Accounting Accountant Fees and Services.

The information required by this Item 14 is incorporated herein by reference to information in our 2023 2024 Proxy Statement, including under heading “Independent Accountants.”

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The financial statements and schedule filed herewith are set forth on the Index to Financial Statements and Schedule of the separate financial section of this annual report, which is incorporated herein by reference.

(b) Exhibits

The following documents are filed as part of this report or were previously filed and incorporated herein by reference to the filing indicated.

3.1	Certificate of Incorporation, dated as of August 28, 2019 (Exhibit (Exhibit 3.3 to the Company's Form 8-K filed August 30, 2019).
3.2	Certificate of Amendment to Certificate of Incorporation of Rockwell Medical, Inc. related to the Reverse Stock Split, dated May 12, 2022 (Exhibit 3.1 to the Company's Form 8-K filed on May 13, 2022).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock (Exhibit 3.1 to the Company's Form 8-K filed on April 8, 2022).
3.4	Amended and Restated Bylaws (Exhibit 3.1 to the Company's Form 10-Q filed November 14, 2022).
4.1	Form of Common Stock Warrant, dated October 17, 2018 (Exhibit 4.1 to the Company's Form 8-K filed October 19, 2018).
4.2	Description of Securities (Exhibit 4.2 to the Company's Form 10-K filed on April 8, 2022)
4.3 4.2	Form of Warrant (Exhibit (Exhibit 4.1 to the Company's Form 8-K filed on September 25, 2020).
4.4 4.3	Form of Pre-Funded Warrant (Exhibit (Exhibit 4.2 to the Company's Form 8-K filed on September 25, 2020).
4.5 4.4	Form of Warrant to Purchase Common Stock for Innovatus (Exhibit (Exhibit 4.1 to the Company's Form 8-K filed March 20, 2020).
4.6 4.5	Form of Pre-Funded Warrant (Exhibit 4.1 to the Company's Form 8-K filed on June 2, 2022).
4.7 4.6	Form of PIPE Warrant (Exhibit 4.2 to the Company's Form 8-K filed on June 2, 2022).
4.8 4.7	Form of PIPE Pre-Funded Warrant (Exhibit 4.3 to the Company's Form 8-K filed on June 2, 2022).
4.8	Common Stock Purchase Warrant, dated July 10, 2023, issued to Armistice Capital Master Fund Ltd. (Exhibit 4.1 to the Company's Form 10-Q filed on August 14, 2023).
4.9	Form of January 2024 Warrant to Purchase Common Stock issued to Innovatus Life Sciences Lending Fund I, LP (Exhibit 4.1 to the Company's Form 8-K filed on January 8, 2024).
10.1	Registration Rights Agreement, dated October 17, 2018 (Exhibit 10.83 Third Amendment to the Company's Form 8-K filed October 19, 2018).
10.2	and Restatement of Loan and Security Agreement, dated March 16, 2020 January 1, 2024, by and among the Company, Rockwell Transportation, Inc., Innovatus Life Sciences Lending Fund I, LP and the lenders party thereto (Exhibit 10.1 to the Company's Form 10-Q filed on May 11, 2020).
10.3	First Amendment to Loan and Security Agreement, dated September 24, 2021, by and among the Company, Innovatus Life Sciences Lending Fund I, LP and the lenders party thereto (Exhibit 10.1 to the Company's Company's Form 8-K filed on September 30, 2021) January 8, 2024).
10.4 10.2	Second Amendment to Loan and Security Agreement dated November 10, 2022 by and among the Company, Innovatus Life Sciences Lending Fund I, LP and the lenders party thereto (Exhibit 10.3 to the Company's Form 10-Q filed on November 14, 2022).
10.5	Sales Agreement, dated April 8, 2022, between Rockwell Medical, Inc. and Cantor Fitzgerald & Co. (Exhibit 1.1 to the Company's Form 8-K filed on April 8, 2022).
10.6 10.3	Securities Purchase Agreement, dated April 6, 2022, by and between the Company and DaVita, Inc. (Exhibit 10.1 to the Company's Form 10-Q filed on May 16, 2022).
10.7 10.4	RD Securities Purchase Agreement, dated May 30, 2022, by and between the Company and the Purchaser signatory therein (Exhibit 10.1 to the Company's Form 8-K filed on June 2, 2022).
10.8 10.5	PIPE Securities Purchase Agreement, dated May 30, 2022, by and between the Company and the Purchaser signatory therein (Exhibit 10.2 to the Company's Form 8-K filed on June 2, 2022).
10.6	Letter Agreement, dated July 10, 2023, by and between Rockwell Medical, Inc. and Armistice Capital Master Fund Ltd. (Exhibit 10.2 to the Company's Form 10-Q filed on August 14, 2023).
10.9 10.7	Registration Rights Agreement, dated June 2, 2022, by and between the Company and the Holder signatory thereto (Exhibit 10.3 to the Company's Form 8-K filed on June 2, 2022).
10.10+	Products Purchase Agreement, dated July 1, 2019, by and between the Company and DaVita Inc. (f/k/a DaVita Healthcare Partners Inc.) (Exhibit 10.1 to the Company's Form 10-Q filed November 12, 2019).
10.11+	Amendment One to Products Purchase Agreement, dated April 6, 2022, by and between the Company and DaVita, Inc. (Exhibit 10.2 to the Company's Form 10-Q filed on May 16, 2022).
10.12	Exclusive Distribution Agreement, dated October 2, 2014, by and between the Company and Baxter Healthcare Corporation (with certain portions redacted pursuant to a confidential treatment order) (Exhibit 10.57 to the Company's Form 10-K filed March 3, 2015).

10.13		Investment Agreement, dated October 2, 2014, by and between the Company and Baxter Healthcare Corporation (Exhibit 10.58 to the Company's Form 10-K filed March 3, 2015).
10.14		First Amendment to Exclusive Distribution Agreement, dated June 23, 2017, by and between the Company and Baxter Healthcare Corporation (with certain portions redacted pursuant to a confidential treatment request) (Exhibit Company's Form 10-Q filed August 9, 2017).
10.15+#		Distribution Termination and Acquisition Agreement dated November 8, 2022 between the Company and Baxter Healthcare Corporation.
10.16+	10.8+	Licensing Agreement, dated January 7, 2002, by and among the Company, Charak LLC and Dr. Ajay Gupta (Exhibit 10.18 to the Company's Form 10-KSB filed April 1, 2002).
10.17	10.9	Amending Agreement, dated January 16, 2006, by and among the Company, Charak LLC and Dr. Ajay Gupta (Exhibit 10.13 to the Company's Form 10-KSB filed March 21, 2006).
10.18	10.10	Master Services and IP Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.34 Company's Form 10-K filed on March 18, 2019).
10.19	10.11	Amendment to License Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.35 to the Company's Form 10-K filed on March 18, 2019).
10.20	10.12	Commercialization and Technology License Agreement IV Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.36 to the Company's Form 10-K filed on March 18, 2019).

10.21	10.13	Technology License Agreement TPN Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.37 to the Company's Form 10-K filed on March 18, 2019).
	10.14	Asset Purchase Agreement dated July 10, 2023 by and between Rockwell Medical, Inc. and Evoqua Water Technologies LLC (Exhibit 10.2 to the Company's Form 10-Q filed on August 14, 2023).
10.22*	10.15+	Amended and Restated Products Purchase Agreement dated September 18, 2023 by and between Rockwell Medical, Inc. and DaVita Inc. (Exhibit 10.1 to the Company's Form 10-Q filed on November 14, 2023).
	10.16*	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective May 21, 2015 (Appendix (Appendix to the Company's Proxy Statement for the 2015 Annual Meeting of Shareholders filed on April 13, 2015).
10.23*	10.17*	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Director Version) (Exhibit (Exhibit 10.22 to the Company's Form 8-K filed December 20, 2007).
10.24*	10.18*	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Employee Version) (Exhibit 10.2310.23 to the Company's Form 8-K filed December 20, 2007).
10.25*	10.19*	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Director Version) (Exhibit (Exhibit 10.62 to the Company's Form 10-K filed February 29, 2016).
	10.26*	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Executive Version) (Exhibit 10.54 to the Company's Form 10-Q filed May 12, 2014).
	10.27*	Form of Performance Share Award Agreement March 2017 (Executive Version) (Exhibit 10.64 to the Company's Form 10-Q filed May 9, 2017).
10.28*	10.20*	Form of Performance Share Award Agreement March 2017 (Director Version) (Exhibit 10.65 (Exhibit 10.65 to the Company's Form 10-Q filed May 9, 2017).
10.29*	10.21*	Rockwell Medical, Inc. Amended and Restated 2018 Long Term Incentive Plan (Exhibit 10.8 10.3 to the Company's Form 10-Q filed on August 15, 2022 August 14, 2023).
10.30*	10.22*	Form of Stock Option Agreement (2018 Long Term Incentive Plan) (Exhibit (Exhibit 10.2 to the Company's Form 10-Q10-Q filed on November 14, 2022). November 14, 2022).
10.31*	10.23*	Form of Contingent Option Agreement for Directors (2018 Long Term Incentive Plan) (Exhibit 10.76 (Exhibit 10.76 to the Company's Form 8-K filed March 21, 2018).
10.32*#	10.24*	Form of Restricted Stock Unit Award Agreement Employee Version (2018 Long Term Incentive Plan).
10.33*#	10.25*	Form of Restricted Stock Unit Award Agreement Director Version (2018 Long Term Incentive Plan).
10.34*	10.26*	Rockwell Medical, Inc. Short Term Incentive Plan (Exhibit 10.1 to the Company's Form 10-Q filed on November 14, 2022).
10.35*	10.27*	Form of Indemnification Agreement (Exhibit (Exhibit 10.1 to the Company's Form 8-K filed August 30, 2019).
10.36*	10.28*	Stock Appreciation Right Agreement, dated September 5, 2017, by and between the Company and John G. Cooper (Exhibit 10.71 (Exhibit 10.71 to the Company's Form 10-Q filed November 8, 2017).
10.37*	10.29*	Employment Agreement, dated June 21, 2022, between Rockwell Medical, Inc. and Mark Strobeck (Exhibit 10.7 to the Company's Form 10-Q filed on August 15, 2022).
10.38*	10.30*#	Russell Ellison Employment Agreement dated April 17, 2020 (Exhibit 10.1 to the Company's Form 8-K filed on April 20, 2020). July 21, 2021 between Rockwell Medical, Inc. and Megan Timmins.
10.39*	10.31#	Russell Skibsted Employment Agreement, dated September 15, 2020 (Exhibit 10.1 to the Company's Form 8-K filed on September 16, 2020). Rockwell Medical, Inc. Amended and Restated Clawback Policy.
	10.32#	Rockwell Medical, Inc. Statement of Company Policy Prohibiting Insider Trading.
	21.1	List of Subsidiaries (Company's Form 10-K filed on March 31, 2021).
	23.1#	Consent of EisnerAmper LLP.
23.1#	23.2#	Consent of Marcum LLP.
	31.1#	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a).
	32.1#	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Database
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2021, formatted in Inline XBRL (included as Exhibit 101)

* Indicates management contracts or compensatory plans or arrangements.
\+ Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.
\# Filed herewith

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ROCKWELL MEDICAL, INC. (Registrant)

By: /s/ Mark Strobeck

Mark Strobeck

President and Chief Executive Officer

Date: March 30, 2023 21, 2024

POWER OF ATTORNEY

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark Strobeck and Megan Timmins, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all documents in connection therewith, with the Securities and Exchange commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their and his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Mark Strobeck Mark Strobeck	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	March 30, 2023 21, 2024
/s/ Paul McGarry Jesse Neri Paul McGarry Jesse Neri	Senior Vice President, Finance and Chief Principal Accounting Officer	March 30, 2023 21, 2024
/s/ John G. Cooper John G. Cooper	Director	March 30, 2023 21, 2024
/s/ Joan Lau Joan Lau	Director	March 21, 2024
/s/ Allen Nissenson Allen Nissenson	Director	March 21, 2024
/s/ Robert S. Radie Robert S. Radie	Director	March 30, 2023 21, 2024
/s/ Allen Nissenson Mark H. Ravich Allen Nissenson Mark H. Ravich	Director	March 30, 2023 21, 2024
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Director	March 30, 2023 21, 2024

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

- EISNERAMPER LLP

To the Stockholders and Board of Directors and Stockholders of
Rockwell Medical, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets sheet of Rockwell Medical, Inc. and Subsidiaries (the "Company") as of December 31, 2022 December 31, 2023, and 2021, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period year then ended, December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 December 31, 2023, and 2021, the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of the intangible asset acquired in the Evoqua asset acquisition

As described in Notes 3 and 4 to the consolidated financial statements, on July 10, 2023, the Company executed and consummated the transactions contemplated by an Asset Purchase Agreement (the "Purchase Agreement") with Evoqua Water Technologies, LLC ("Evoqua")(the "Evoqua Acquisition"). At the closing of the transaction, the Company acquired assets, including an intangible asset, from Evoqua for consideration of $17.4 million and the transaction was accounted for as an asset acquisition. The acquired intangible asset was a customer list valued on a relative fair value basis at $11.0 million on the acquisition date. Establishing the relative fair value of the customer list intangible asset required management to first perform a fair value assessment, which was completed using a multi-period excess earnings method ("MPEEM"). The method used to estimate the fair value of the acquired intangible asset involved significant assumptions. The significant assumptions applied by the Company in estimating the fair value of the acquired customer list intangible asset included cash flow projections, discount rates, and the estimated useful life of the customer relationships.

We identified the valuation of the acquired customer list intangible asset as a critical audit matter due to the significant judgement by management involved with developing the estimates to determine the fair value of the customer list intangible asset, specifically those relating to the projected cash flows, discount rates, and the estimated useful life of the customer relationships. As such, there was a high degree of auditor judgement and subjectivity, and significant audit effort was required in performing procedures to evaluate management's conclusions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures include, among others, (i) obtaining an understanding of and evaluating the design of controls related to the valuation of the acquired customer list intangible asset; and (ii) reading the Purchase Agreement and testing management's process for estimating the fair value of the acquired customer list intangible asset, which included evaluating the appropriateness of the valuation models, testing the completeness, accuracy, and relevance of underlying data used in the models, and testing the reasonableness of significant assumptions, including cash flow projections, discount rates, and the estimated useful life of the customer relationships. Evaluating the cash flow projections involved considering the current performance of the acquired assets, the consistency with external market and industry data, and whether these assumptions were consistent with other evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating the reasonableness of the significant assumptions, including discount rates and the estimated useful life of customer relationships.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2023.

EISNERAMPER LLP
West Palm Beach, Florida
March 21, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - MARCUM LLP

To the Stockholders and Board of Directors of
Rockwell Medical Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Rockwell Medical Inc. and Subsidiaries (the “Company”) as of December 31, 2022, the related consolidated statement of operations, comprehensive loss, changes in stockholders’ equity and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022, and the consolidated results of its operations and its cash flows for each of the two years in the period year then ended, December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of Going Concern

As disclosed in Note 2 to the consolidated financial statements, the Company has experienced significant net losses since inception, has an accumulated deficit and has used significant cash flows for operations during 2022, which caused management to evaluate if those factors raised substantial doubt about the Company’s ability to continue as a going concern which could be mitigated through Management’s plan. Management’s plan as disclosed in Note 2

includes increasing prices with some of its customers, entering into new distribution and purchase agreements with former Baxter customers, restructuring the Company’s contract with its largest customer in the concentrates business, and implementing certain cost cutting and containment measures, all of which are significant assumptions in the Company’s projections used in its evaluation of going concern. The Company’s management has exercised significant judgment in their determination of how existing accounting principles generally accepted in the United States of America should be applied to the evaluation of going concern, the associated financial statement presentation and note disclosures relating to substantial doubt about the Company’s ability to continue as a going concern.

We identified the evaluation of the Company’s ability to continue as a going concern as a critical audit matter due to the nature and extent of audit effort required to obtain sufficient appropriate audit evidence to address the risks of material misstatement related to the disclosure of the Company’s liquidity and ability to continue as a going concern for at least the next twelve months in the consolidated financial statements. The nature and extent of audit effort required to address the matter included significant involvement of more experienced engagement team members. The primary procedures we performed to address this critical audit matter included the following:

- Understand management's process and related internal controls in conducting the evaluation of going concern, including preparing projections.
- We examined the executed Amendment to the Products Purchase Agreement and analyzed the terms in the agreement to the projected financial information, such as the projected revenue and gross margins.
- We evaluated and tested management's assumptions, including, but not limited to, projected price increases to subsequent customer activity to validate the significant assumptions in the projected financial information, such as the projected revenue, gross margins, growth rates and operating expenses.
- We examined the executed Distribution Termination and Acquisition Agreement and analyzed the terms in the agreement to the significant assumptions in the projected financial information, such as the projected revenue and gross margins from customers reacquired under this agreement.
- We examined the executed Second Amendment to the Loan and Security Agreement and tested management's inputs and calculations of compliance with the projected required financial covenants, such as, concentrate revenue and minimum cash requirements.
- We tested certain assumptions for reasonableness to test the changes to the expected cash flows.
- We concluded on the probability of success of management's plan.

/s/ Marcum LLP
Marcum LLP
(PCAOB ID 688)

We have served as the Company's auditor since 2018. from 2018 to 2023.

Chicago, Illinois
March 30, 2023

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Dollars in Thousands) In thousands, except share and par value amounts)

		December 31, 2022	December 31, 2021			
December 31, 2023				December 31, 2023	December 31, 2022	
ASSETS	**ASSETS**					
Cash and Cash Equivalents	Cash and Cash Equivalents	$ 10,102	$ 13,280			
Cash and Cash Equivalents						
Cash and Cash Equivalents						
Investments Available-for-Sale	Investments Available-for-Sale	11,390	9,158			
Accounts Receivable, net of a reserve of $33 for 2022 and $16 for 2021		6,259	5,913			
Inventory		5,814	4,076			
Accounts Receivable, net of a reserve of $81 for 2023 and $33 for 2022						
Inventory, net						
Prepaid and Other Current Assets	Prepaid and Other Current Assets	1,745	2,861			
Total Current Assets	**Total Current Assets**	**35,310**	**35,288**			
Property and Equipment, net	Property and Equipment, net	2,194	2,486			
Inventory, Non-Current	Inventory, Non-Current	1,276	1,523			
Right of Use Assets, net		6,411	7,737			

Right of Use Assets - Operating, net			
Right of Use Assets - Financing, net			
Intangible Assets, net			
Goodwill	Goodwill	921	921
Other Non-Current Assets	Other Non-Current Assets	523	619
Total Assets	**Total Assets**	**$ 46,635**	**$ 48,574**
LIABILITIES AND STOCKHOLDERS' EQUITY	**LIABILITIES AND STOCKHOLDERS' EQUITY**		
Insurance Financing Note Payable			
Insurance Financing Note Payable			
Insurance Financing Note Payable			
Accounts Payable	Accounts Payable	$ 4,053	$ 3,739
Accrued Liabilities	Accrued Liabilities	7,702	5,090
Lease Liability - Current		2,005	2,004
Deferred License Revenue		1,731	2,171
Term Loan - Net of Issuance Costs		1,631	7,381
Insurance Financing Note Payable		503	437
Deferred Consideration, Current			
Lease Liabilities - Operating, Current			
Lease Liabilities - Financing, Current			
Deferred License Revenue, Current			
Term Loan, Current - Net of Issuance Costs and Premium Accretion			
Customer Deposits	Customer Deposits	66	144
Total Current Liabilities	**Total Current Liabilities**	**17,691**	**20,966**
Lease Liability - Long-Term		4,669	5,887
Term Loan, Net of Issuance Costs		7,555	13,186
Lease Liabilities - Operating - Long-Term			
Lease Liabilities - Operating - Long-Term			
Lease Liabilities - Operating - Long-Term			
Lease Liabilities - Financing - Long-Term			
Term Loan - Long-Term, Net of Issuance Costs and Premium Accretion			
Deferred License Revenue - Long-Term	Deferred License Revenue - Long-Term	2,600	5,986
Deferred Consideration - Long-Term			

Long Term Liability - Other	Long Term Liability - Other	14	14
Total Liabilities	**Total Liabilities**	**32,529**	**46,039**
Commitments and Contingencies (See Note 14)			
Commitments and Contingencies (See Note 15)			
Commitments and Contingencies (See Note 15)			
Commitments and Contingencies (See Note 15)			
Stockholders' Equity:	**Stockholders' Equity:**		
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, 15,000 and nil shares issued and outstanding at December 31, 2022 and 2021, respectively		—	—
Common Stock, $0.0001 par value, 170,000,000 shares authorized, 12,163,673 and 8,544,225 shares issued and outstanding at December 31, 2022 and 2021, respectively		1	1
Stockholders' Equity:			
Stockholders' Equity:			
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, 15,000 shares issued and outstanding at December 31, 2023 and 2022			
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, 15,000 shares issued and outstanding at December 31, 2023 and 2022			
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, 15,000 shares issued and outstanding at December 31, 2023 and 2022			
Common Stock, $0.0001 par value, 170,000,000 shares authorized, 29,130,607 and 12,163,673 shares issued and outstanding at December 31, 2023 and 2022			
Additional Paid-in Capital	Additional Paid-in Capital	402,701	372,562
Accumulated Deficit	Accumulated Deficit	(388,759)	(370,080)
Accumulated Other Comprehensive Income		163	52
Total Stockholders' Equity		**14,106**	**2,535**
Total Liabilities and Stockholders' Equity		**$ 46,635**	**$ 48,574**
Accumulated Other Comprehensive (Loss) Income			

Total Stockholders' Equity	**21,291**	**14,106**
Total Liabilities and Stockholders' Equity	**$ 52,173**	**$ 46,635**

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For The Years Ended December 31, 2022 and 2021
(Dollars in In thousands, except share and per share amounts)

	2022	2021
	Years Ended December 31,	
	2023	
	2023	2022
Net Sales	**Net Sales**	**$ 72,810**	**$ 61,931**
Net Sales		
Net Sales		
Cost of Sales	Cost of Sales	68,733	64,351
Gross (Loss) Profit		4,077	(2,420)
Gross Profit			
Research and Product Development	Research and Product Development	3,119	6,835
Selling and Marketing	Selling and Marketing	2,094	5,733
General and Administrative	General and Administrative	15,644	15,348
Operating Loss	**Operating Loss**	**(16,780)**	**(30,336)**
Other Expense			
Other Expense:			
Other Expense:			
Other Expense:			
Realized Gain on Investments			
Realized Gain on Investments			
Realized Gain on Investments	Realized Gain on Investments	4	—
Interest Expense			
Interest Expense			
Interest Expense	Interest Expense	(1,936)	(2,360)
Interest Income	Interest Income	33	22
Total Other Expense		**(1,899)**	**(2,338)**
Total Other Expense, net			
Total Other Expense, net			
Total Other Expense, net			
Net Loss	**Net Loss**	**$ (18,679)**	**$ (32,674)**
Net Loss			
Net Loss			
Basic and Diluted Net Loss per Share		**$ (1.89)**	**$ (3.83)**

Basic and Diluted Weighted Average Shares Outstanding	**9,866,844**	**8,526,186**			
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted					
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted					
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted					
Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted			**Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted**	**23,322,915**	**14,304,512**

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

For The Years Ended December 31, 2022 and 2021

(Dollars in Thousands) In thousands)

		2022	**2021**		
	Years Ended December 31,			**Years Ended December 31,**	
	2023			**2023**	**2022**
Net Loss	**Net Loss**	**$(18,679)**	**$(32,674)**		
Unrealized Gain (Loss) on Available-for-Sale Investments		114	(6)		
Unrealized (Loss) Gain on Available-for-Sale Investments					
Foreign Currency Translation Adjustments	Foreign Currency Translation Adjustments	(3)	1		
Comprehensive Loss	**Comprehensive Loss**	**$(18,568)**	**$(32,679)**		

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

For The Years Ended December 31, 2022 and 2021 (In thousands, except share amounts)

(Dollars in Thousand)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME / (LOSS)	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT				
Balance as of January 1, 2021	**—**	**$ —**	**8,506,651**	**$ 1**	**$ 371,518**	**$ (337,406)**	**$ 57**	**$ 34,170**
Net Loss	—	—	—	—	—	(32,674)	—	(32,674)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	—	—	(6)	(6)
Foreign Currency Translation Adjustments	—	—	—	—	—	—	1	1
Vesting of Restricted Stock Units Issued, net of taxes withheld	—	—	23,483	—	(6)	—	—	(6)
Warrant Modification Expense	—	—	14,091	—	107	—	—	107
Stock-based Compensation	—	—	—	—	943	—	—	943
Balance as of December 31, 2021	**—**	**$ —**	**8,544,225**	**$ 1**	**$ 372,562**	**$ (370,080)**	**$ 52**	**$ 2,535**

	PREFERRED STOCK								COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT
	SHARES								SHARES	AMOUNT		
Balance as of January 1, 2022												
Net Loss	Net Loss	—	—	—	—	—	(18,679)	—	(18,679)			
Unrealized Loss on Available-for-Sale Investments	Unrealized Loss on Available-for-Sale Investments	—	—	—	—	—	—	114	114			
Foreign Currency Translation Adjustments	Foreign Currency Translation Adjustments	—	—	—	—	—	—	(3)	(3)			
Vesting of Restricted Stock Units Issued, net of taxes withheld	Vesting of Restricted Stock Units Issued, net of taxes withheld	—	—	10,958	—	—	—	—	—			
Issuance of Common Stock, net of Issuance Costs / Public offering	Issuance of Common Stock, net of Issuance Costs / Public offering	—	—	844,613	—	14,893	—	—	14,893			
Issuance of Common Stock, net of Issuance Costs / At-the-market offerings	Issuance of Common Stock, net of Issuance Costs / At-the-market offerings	—	—	7,500	—	15	—	—	15			
Issuance of preferred stock, net of offering costs		15,000	—	—	—	14,916	—	—	14,916			
Issuance of common stock upon exercise of prefunded warrants		—	—	2,756,377	—	—	—	—	—			

Issuance of Preferred Stock, net of offering costs									
Issuance of Common Stock upon exercise of Pre-Funded Warrants									
Stock-based Compensation	Stock-based Compensation	—	—	—	—	315	—	—	315
Stock-based Compensation	Stock-based Compensation								
Balance as of December 31, 2022	**Balance as of December 31, 2022**	**15,000**	**$ —**	**12,163,673**	**$ 1**	**$ 402,701**	**$ (388,759)**	**$ 163**	**$ 14,106**
Net Loss									
Unrealized Loss on Available-for-Sale Investments									
Foreign Currency Translation Adjustments									
Vesting of Restricted Stock Units Issued, net of taxes withheld									
Issuance of Common Stock in connection with exercise of Prior Warrant and Pre-Funded Warrants, net of offering costs									
Issuance of Common Stock in connection with exercise of Prior Warrant and Pre-Funded Warrants, net of offering costs									
Issuance of Common Stock in connection with exercise of Prior Warrant and Pre-Funded Warrants, net of offering costs									
Issuance of Common Stock, net of Issuance Costs / At-the-market offerings									
Stock-based Compensation									
Stock-based Compensation									

Stock-based Compensation	
Balance as of December 31, 2023	

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For The Years Ended December 31, 2022 and 2021 (In thousands)

(Dollars in Thousands)

	2022	2021
Cash Flows From Operating Activities:		
Net Loss	**$ (18,679)**	**$ (32,674)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	576	668
Stock-based Compensation	315	943
Increase in Inventory Reserves	610	146
Amortization of Right of Use Asset	2,013	1,847
Amortization of Debt Financing Costs and Accretion of Debt Discount	369	369
Loss on Disposal of Assets	(3)	8
Realized Loss on Sale of Investments Available-for-Sale	(4)	—
Foreign Currency Translation Adjustment	(3)	2
Changes in Assets and Liabilities:		
Increase in Accounts Receivable, net	(346)	(1,742)
Increase in Inventory	(2,101)	(656)
Decrease in Other Assets	2,720	1,823
(Decrease) Increase in Accounts Payable	314	(416)
Decrease in Lease Liability	(1,903)	(1,771)
(Decrease) Increase in Other Liabilities	2,534	(48)
Decrease in Deferred License Revenue	(3,826)	(2,033)
Changes in Assets and Liabilities	(2,608)	(4,843)
Cash Used In Operating Activities	**(17,414)**	**(33,534)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(21,297)	(26,058)
Sale of Investments Available-for-Sale	19,182	26,891
Purchase of Equipment	(281)	(522)
Cash (Used In) Provided By Investing Activities	**(2,396)**	**311**
Cash Flows From Financing Activities:		
Payments on Short Term Note Payable	(1,443)	(1,530)
Payments on Debt	(11,750)	(750)
Proceeds from the Issuance of Common Stock / Public Offering	15,016	—
Offering Costs from the Issuance of Common Stock / Public Offering	(106)	—
Proceeds from the Issuance of Common Stock / At-the Market Offerings	15,000	—
Offering Costs from the Issuance of Common Stock / At-the Market Offerings	(85)	—
Proceeds from issuance of Common Stock for payment related to services provided	—	107
Repurchase of Common Stock to Pay Employee Withholding Taxes	—	(6)
Cash Provided By (Used in) Financing Activities	**16,632**	**(2,179)**
Decrease In Cash and Cash Equivalents	(3,178)	(35,402)
Cash and Cash Equivalents At Beginning Of Period	13,280	48,682

Cash and Cash Equivalents At End Of Period	**$ 10,102**	**$ 13,280**
Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 1,470	$ 1,827
Supplemental Disclosure of Noncash Investing Activities:		
Change in Unrealized Loss on Marketable Securities Available-for-Sale	$ 114	$ (6)
Insurance Financing Note Payable	$ 503	$ 437
Fair Value of Warrants issued related to Debt Financing	$ 501	$ 501

	Years Ended December 31,	
	2023	**2022**
Cash Flows From Operating Activities:		
Net Loss	**$ (8,439)**	**$ (18,679)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	1,444	576
Stock-based Compensation	932	315
Increase in Inventory Reserves	1,098	610
Non-cash Lease Expense from Right of Use Assets	2,010	2,013
Amortization of Debt Financing Costs and Accretion of Debt Discount and Premium	1,107	369
Loss (Gain) on Disposal of Assets	1	(3)
Realized Gain on Sale of Investments	(321)	(4)
Changes in Assets and Liabilities:		
Accounts Receivable, net	(4,642)	(346)
Inventory	1,176	(2,101)
Prepaid and Other Assets	1,410	2,720
Accounts Payable	463	314
Lease Liabilities	(1,465)	(1,421)
Accrued and Other Liabilities	(376)	2,534
Deferred License Revenue	(3,810)	(3,826)
Changes in Operating Assets and Liabilities	(7,244)	(2,126)
Cash Used In Operating Activities	**(9,412)**	**(16,929)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(5,701)	(21,297)
Sale of Investments Available-for-Sale	15,301	19,182
Purchase of Equipment	(284)	(281)
Cash Paid in Connection with Evoqua Asset Acquisition	(12,361)	—
Cash Used In Investing Activities	**(3,045)**	**(2,396)**
Cash Flows From Financing Activities:		
Payments on Debt	(2,000)	(11,750)
Payments on Insurance Financing Note Payable	(992)	(1,443)
Payments on Financing Lease Liabilities	(522)	(482)
Proceeds from Issuance of Common Stock	14,861	15,016
Offering Costs from Issuance of Common Stock	(5)	(106)
Proceeds from Issuance of Preferred Stock	—	15,000
Offering Costs from Issuance of Preferred Stock	—	(85)
Cash Provided By Financing Activities	**11,342**	**16,150**
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(4)	(3)
Decrease In Cash and Cash Equivalents	(1,119)	(3,178)
Cash and Cash Equivalents At Beginning Of Year	10,102	13,280
Cash and Cash Equivalents At End Of Year	**$ 8,983**	**$ 10,102**

Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 1,209	$ 1,470
Supplemental Disclosure of Noncash Investing and Financing Activities:		
Change in Unrealized (Loss) Gain on Marketable Securities Available-for-Sale	$ (159)	$ 114
Increase in Prepaid Assets from Insurance Financing Note Payable	$ 733	$ 503
Fair Value of Warrants issued related to Debt Financing	$ —	$ 501
Deferred Consideration from Evoqua Asset Acquisition	$ 5,000	$ —

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Description of Business

Rockwell Medical, Inc. (the "Company", "Rockwell", "we", or "us") is a healthcare company that develops, manufactures, commercializes, and distributes a portfolio of hemodialysis products for dialysis providers worldwide.

Rockwell is a revenue-generating business and the second largest supplier of liquid and powder acid and bicarbonate concentrates for dialysis patients in the United States. Hemodialysis is the most common form of end-stage kidney disease treatment and is usually typically performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient's home. This represents a large market opportunity for which Rockwell's products are well-positioned to meet the needs of patients.

Rockwell provides the hemodialysis community with products controlled by a Quality Management System regulated by the U.S. Food and Drug Administration ("FDA"). Rockwell manufactures hemodialysis concentrates under Current Good Manufacturing Practices ("cGMP") regulations at its three facilities in Michigan, Texas, South Carolina and South Carolina Texas totaling approximately 175,000 square feet, and manufactures its dry acid concentrate mixers at its facility in Iowa. Rockwell delivers the majority of its hemodialysis concentrates products and mixers to dialysis clinics throughout the United States and internationally utilizing its own delivery trucks and third-party carriers. Rockwell has developed a core expertise in

On July 10, 2023, the Company executed and consummated the transactions contemplated by an Asset Purchase Agreement (the "Purchase Agreement") with Evoqua Water Technologies LLC ("Evoqua") (the "Evoqua Acquisition"). Subject to the terms and conditions of the Purchase Agreement, at the closing of the transaction (the "Closing"), the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to its manufacturing and delivering selling of hemodialysis concentrates and has built products, all of which are manufactured under a longstanding reputation contract manufacturing agreement with a third-party organization. See Note 4 for reliability, quality, and excellent customer service. further detail.

In addition to its primary focus on hemodialysis concentrates, Rockwell also has a proprietary parenteral iron product, Triferic® (ferric pyrophosphate citrate ("FPC")), which is indicated to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. While Rockwell has discontinued commercialization of Triferic in the United States, the Company has had established several international partnerships with companies seeking and sought to develop and commercialize Triferic outside the United States and is was working closely with these international partners to develop and commercialize Triferic in their respective regions. During the year ended December 31, 2023, the ongoing Triferic development effort was terminated resulting in an acceleration of the corresponding deferred license revenue (see Note 10) and a reserve on the non-current inventory (see Note 7). Additionally, Rockwell continues to evaluate the viability of its FPC platform and FPC's potential to treat iron deficiency, iron deficiency anemia, and acute heart failure.

Rockwell was incorporated in the state of Michigan in 1996 and re-domiciled to the state of Delaware in 2019. Rockwell's headquarters is located at 30142 Wixom Road, Wixom, Michigan 48393.

Note 2. Liquidity and Going Concern Considerations

Since inception, Rockwell has incurred significant net losses and has funded its operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. At December 31, 2022 December 31, 2023, Rockwell had an accumulated deficit of approximately $388.8 million $397.2 million and stockholders' equity of $14.1 $21.3 million. As of December 31, 2022 December 31, 2023, Rockwell had approximately $21.5 million $10.9 million of cash, cash equivalents and investments available-for-sale, and working capital of $17.6 million $12.1 million. Net cash used in operating activities for the year ended December 31, 2022 December 31, 2023 was approximately $17.4 million. These factors raised substantial doubt about the Company's ability to continue as a going concern and depended, in part, on the degree of success in addressing inflationary pressures affecting the Company's concentrates business, as well as the Company's ability to contain costs, raise additional working capital, if needed, and remain in compliance with financial and reporting covenants under the Company's secured loan.

On April 6, 2022, the Company and DaVita, Inc. ("DaVita") entered into an amendment (the "Amendment") to the Products Purchase Agreement, dated July 1, 2019, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amendment, the Company and DaVita agreed to certain price increases, effective May 1, 2022, as well as the pass-through of certain inflationary costs, determined on a quarterly basis. Certain costs are subject to a cap. The Amendment also requires the Company to implement certain cost containment and cost-cutting measures. The Amendment contains certain covenants with respect to the Company's ongoing operations, including a minimum cash covenant of $10 million, or the Company will be in default under the Products Purchase Agreement. An event of default could result in termination of that agreement.

On April 6, 2022, the Company and DaVita entered into a Securities Purchase Agreement (the "SPA"), pursuant to which the Company issued $15 million of preferred stock to DaVita in two separate tranches. The Company initially issued 7,500 shares of a newly designated series of preferred stock, which is designated "Series X Convertible Preferred Stock" (the "Series X Preferred Stock") for gross proceeds of $7,500,000. On June 15, 2022, the Company issued to DaVita an additional 7,500 shares of Series X Preferred Stock in a second closing (the "Second Tranche") for an additional $7,500,000. The Second

Tranche was conditioned upon the Company raising an additional $15,000,000 in capital within a certain timeline, which took place on June 2, 2022 $9.4 million.

On April 8, 2022, the Company entered into a sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time up to $12,200,000 of shares of Company's common stock through the Agent. During the year ended December 31, 2022, the Company sold 7,500 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $15,135, at a weighted average selling price of approximately $2.02 The Company paid $378 in commissions and offering fees. Approximately $12.2 million remains available for sale under the ATM facility.

On May 30, 2022, the Company entered into a Securities Purchase Agreement (the "RD Purchase Agreement") with the purchaser named therein (the "Purchaser"), pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Offering"), 844,613 shares of its common stock at price of $1.39 per share, and prefunded warrants to purchase up to an aggregate of 7,788,480 shares of common stock (the "Pre-Funded Warrants" and the shares of common stock underlying the Pre-Funded Warrants, the "Warrant Shares"). The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each Pre-Funded Warrant is $0.0001 per share.

Also on May 30, 2022, concurrently with the Offering, the Company entered into a Securities Purchase Agreement with the Purchaser (the "PIPE Purchase Agreement") relating to the offering and sale (the "Private Placement") of warrants to purchase up to a total of 9,900,990 shares of common stock and pre-funded warrants to purchase up to a total of 1,267,897 shares of common stock (the "PIPE Warrants"). Each warrant was sold at a price of $0.125 per underlying warrant share and is exercisable at an exercise price of 1.39 per share. The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each prefunded warrant is $0.0001 per share. The Offering and the Private Placement closed on June 2, 2022. The net proceeds to the Company from the Offering and the Private Placement were approximately $14.9 million, after deducting fees and expenses.

On November 10, 2022, the Company entered into a Second Amendment to the Loan and Security Agreement (the "Second Amendment") dated as of November 14, 2022 with Innovatus, which amended the Loan Agreement. Pursuant to the Second Amendment, the Company (i) prepaid an aggregate principal amount of $5.0 million in Term Loans (as defined in the Loan Agreement) in one installment on November 14, 2022; (ii) shall pay interest only payments until September 2023 at which time will resume scheduled debt payments (See Note 16 for more information on our debt facility).

Management evaluated it's going concern by reviewing the Company's operational plans which include executing on the projected financial information including price increases, acquisition of new customers, projected growth of margins and cost containment activities. Additionally, the Company's operational plans also include raising capital, if needed, by using our ATM facility or other methods or forms of financings, subject to existing limitations. Based on the currently available working capital and expectation of the ability of management to execute on the Company's operational plans noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report. Accordingly, management believes that the factors noted above which raised substantial doubt about the Company's ability to continue as a going concern have been alleviated.

The Company may require additional capital to sustain its operations and make the investments it needs to execute its strategic plan. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume such financing will be available on favorable terms, if at all.

Currently, because Additionally, the Company's public float is less than $75 plans include raising capital, if needed, by using the $11 million it is remaining on its ATM facility or other methods or forms of financings, subject to the baby shelf limitations under Form S-3, which limits the amount the Company may offer pursuant to its registration statement on Form S-3.

In addition, the Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of December 31, 2022, the Company is in compliance with all financial covenants (See Note 16 for further detail). existing limitations.

Global Economic Conditions - Risks and Uncertainties

The COVID-19 pandemic and resulting domestic and global disruptions, particularly in the supply chain and labor market, among other areas, have adversely affected the Company's business and operations, including, but not limited to, its sales and marketing efforts and its research and development activities, its plant and transportation operations and the operations of third parties upon whom the Company relies. The Company's international business development activities may also continue to be negatively impacted by COVID-19.

In addition, the global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine, Israel-Hamas conflict and other political tensions, and lingering effects the occurrence of the COVID-19 pandemic. natural disasters and public health crises. Such challenges have caused, and may continue to cause, recession fears, rising interest rates, foreign exchange volatility and inflationary pressures. At this time, the Company is unable to quantify the potential effects of this economic instability on our future operations.

Rockwell has utilized a range of financing methods to fund its operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding, refinancing or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect the Company's liquidity and capital resources in the future.

Note 3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Rockwell Transportation, Inc. and Rockwell Medical India Private Limited. Rockwell Medical India Private Limited was formed in 2018 2019 for the purpose of conducting certain commercial activities in India. All intercompany balances and transactions have been eliminated in consolidation.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation, including the reclassification of lease right-of-use assets into Right of Use Assets - Operating, Net and Right of Use Assets - Financing, Net and lease liabilities into Lease Liabilities - Operating, Current, Lease Liabilities - Financing, Current, Lease Liabilities - Operating, Long-Term, and Lease Liabilities - Financing, Long-Term. Additionally, amounts from the Changes in Lease Liabilities were reclassified to Payments on Financing Lease Liabilities on the statement of cash flows.

Revenue Recognition

The Company recognizes revenue under Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers. Customers,* issued by the Financial Accounting Standards Board ("FASB"). The core principle of the revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue.

Shipping and handling costs associated with outbound freight related to contracts with customers are accounted for as a fulfillment cost and are included in cost of sales when control of the goods transfers to the customer.

Nature of goods and services

The following is a description of principal activities from which the Company generates its revenue. For a discussion of significant market segments and customers, see Note 6.

Product sales –Sales

The Company accounts for individual products and services separately if they are distinct (i.e., if a product or service is separately identifiable from other items and if a customer can benefit from it on its own or with other resources that are readily available to the customer). The consideration, including any discounts, is allocated between separate products and services based on their stand-alone selling prices. The stand-alone selling prices are determined based on the cost plus margin approach.

Drug and dialysis concentrate products are sold directly to dialysis clinics and to wholesale distributors in both domestic and international markets. Distribution and license agreements for which upfront fees are received are evaluated upon execution or modification of the agreement to determine if the agreement creates a separate performance obligation from the underlying product sales. For all existing distribution and license agreements, the distribution and license agreement is not a distinct performance obligation from the product sales. In instances where regulatory approval of the product has not been established and the Company does not have sufficient experience with the foreign regulatory

body to conclude that regulatory approval is probable, the revenue for the performance obligation is recognized over the term of the license agreement (over time recognition). Conversely, when regulatory approval already exists or is probable, revenue is recognized at the point in time that control of the product transfers to the customer.

For the majority of the Company's international customers, the Company recognizes revenue at the shipping point, which is generally the Company's plant or warehouse. For other business, the Company recognizes revenue based on when the customer takes control of the product. The amount of revenue recognized is based on the purchase order less returns and adjusted for any rebates, discounts, chargebacks or other amounts paid to customers estimated at the time of sale. Customers typically pay for the product based on customary business practices with payment terms averaging 30 days, while a small subset of customers have payment terms averaging 60 days.

Deferred License Revenue

The Company received upfront fees under five distribution and license agreements that have been deferred as a contract liability. liability and presented on the accompanying consolidated balance sheets as deferred license revenue. The amounts received from Wanbang Biopharmaceuticals Co., Ltd. ("Wanbang"), Sun Pharmaceutical Industries Ltd. ("Sun Pharma"), Jeil Pharmaceutical Co., Ltd. ("Jeil Pharma") and Drogsan Pharmaceuticals ("Drogsan Pharma") are recognized as revenue over the estimated term of the applicable distribution and license agreement as regulatory approval was not received and the Company did not have sufficient experience in China, India, South Korea and Turkey, respectively, to determine that regulatory approval was probable as of the execution of the agreement. During the year ended December 31, 2023, the amounts received from Wanbang were accelerated out of deferred license revenue and into revenue upon notice that the development effort was terminated. The amounts received from Baxter Healthcare Corporation ("Baxter") are were deferred and recognized as revenue at the point in time that the estimated product sales under the agreement occur. occurred. During the year ended December 31, 2023, all remaining deferred revenue relating to the Baxter agreement was recognized as revenue. For additional information related to the Company's deferred license revenue, see Note 10.

Product Purchase Agreements

On November 9, 2022 September 18, 2023, Rockwell reacquired the Company and its distribution rights to its hemodialysis concentrates products from Baxter long-time partner, DaVita, Inc. ("DaVita"), a leading provider of kidney care, entered into an Amended and Restated Products Purchase Agreement (the "Amended Agreement"), which amends and restates the Product Purchase Agreement, dated July 1, 2019, as amended, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amended Agreement, the Company and DaVita agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment of $0.4 million to Rockwell on or after December 1, 2023, which was recorded as revenue recognized during the year ended December 31, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, to further extend the term through December 31, 2025. In the event of such an extension, product pricing will be increased for the extended term. In addition, DaVita is required to provide the Company with nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for the amount forecasted, purchase additional product, or the Company

may terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements Amended Agreement. Upon expiration or termination of the agreement terminated December 31, 2022. Rockwell Amended Agreement, and upon request by DaVita, the Company has agreed to provide certain transition services to DaVita during a group of Baxter customers until March 31, 2023.Remaining upfront fees will continue to be recognized through March 31, 2023 as Rockwell continues to have product sales obligations to a group of specific Baxter customers.

For the majority of the Company's international customers, the Company recognizes revenue at the shipping point, which is generally the Company's plant or warehouse. For other business, the Company recognizes revenue based on when the customer takes control of the product. The amount of revenue recognized is based on the purchase order less returns and adjusted for any rebates, discounts, chargebacks or other amounts paid to customers. There were no such adjustments for the periods reported. Customers typically pay for the product based on customary business practices with payment terms averaging 30 days, while distributor payment terms average 45 days.

transition period.

Disaggregation of revenue

Revenue is disaggregated by primary geographical market, major product line, and timing of revenue recognition.

In thousands of US dollars ($)	Year Ended December 31, 2022		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ 903	$ 561	$ 342
License Fee – Over time	256	—	256
Total Drug Products	1,159	561	598
Concentrate Products			
Product Sales – Point-in-time	69,162	62,715	6,447
License Fee – Over time	2,489	2,489	—
Total Concentrate Products	71,651	65,204	6,447
Net Revenue	$ 72,810	$ 65,765	$ 7,045

In thousands of US dollars ($)	Year Ended December 31, 2021		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ 835	$ 835	$ —
License Fee – Over time	241	—	241
Total Drug Products	1,076	$ 835	241
Concentrate Products			
Product Sales – Point-in-time	58,913	52,614	6,299
License Fee – Over time	1,942	1,942	—
Total Concentrate Products	60,855	54,556	6,299
Net Revenue	$ 61,931	$ 55,391	$ 6,540

For the years ended December 31, 2022 and 2021, license fee revenue was $2.7 million and 2.2 million respectively. For the years ended December 31, 2022 and 2021, product sales revenue was $70.1 million and $59.7 million, respectively.

In thousands	Year Ended December 31, 2023		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ —	$ —	$ —
License Fee – Over time	2,338	—	2,338
Total Drug Products	2,338	—	2,338
Concentrate Products			
Product Sales – Point-in-time	79,802	72,871	6,931
License Fee – Over time	1,472	1,472	—
Total Concentrate Products	81,274	74,343	6,931
Net Revenue	$ 83,612	$ 74,343	$ 9,269

In thousands	Year Ended December 31, 2022		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ 903	$ 561	$ 342
License Fee – Over time	256	—	256
Total Drug Products	1,159	$ 561	598
Concentrate Products			
Product Sales – Point-in-time	69,162	62,715	6,447
License Fee – Over time	2,489	2,489	—
Total Concentrate Products	71,651	65,204	6,447
Net Revenue	$ 72,810	$ 65,765	$ 7,045

Contract balances

The following table provides information about receivables, contract assets, and contract liabilities from contracts with customers.

In thousands of US dollars ($)	December 31, 2022	December 31, 2021
Receivables, which are included in "Trade and other receivables"	$ 6,259	$ 5,913
Contract liabilities	$ 4,331	$ 8,157

In thousands	December 31, 2023	December 31, 2022	January 1, 2022
Accounts Receivable, net	$ 10,901	$ 6,259	$ 5,913
Contract Liabilities, which are included in deferred license revenue	$ 521	$ 4,331	$ 8,157

There were no impairment losses recognized related to any receivables arising from the Company's contracts with customers for the years ended December 31, 2022 and 2021.

For the years ended December 31, 2022 and 2021, the Company did not recognize material bad-debt expense and there were no other material contract assets recorded on the consolidated balance sheets as of December 31, 2022 December 31, 2023 and 2021. 2022. The Company does not generally accept returns of its concentrate products and no reserve for returns of concentrate products was established as of December 31, 2022 December 31, 2023 or 2021. 2022.

The contract liabilities primarily relate to upfront payments fees under distribution and consideration received from customers that are received in advance of the customer assuming control of the related products. license agreements with Baxter, Wanbang, Sun Pharma, Jeil Pharma, and Drogan Pharma.

Transaction price allocated to remaining performance obligations

For each of the years ended December 31, 2023 and 2022, the Company recognized $3.8 million as revenue from amounts classified as contract liabilities (i.e., deferred license revenue) as of December 31, 2022 and 2021, respectively.

For the year ended December 31, 2022, revenue recognized from performance obligations related to prior periods was not material.

Revenue expected to be recognized in any future year related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less, contracts where revenue is recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled $2.9 million $0.5 million and $8.2 million $2.9 million as of December 31, 2022 December 31, 2023 and 2021, 2022, respectively. The amount relates primarily to upfront payments and consideration received from customers that are received in advance of the customer assuming control of the related products. The Company applies the practical expedient in ASC 606, paragraph 606-10-50-14 and does not disclose information about remaining performance obligations that have original expected durations of one year or less.

Reverse Stock Split

On May 9, 2022, the stockholders of the Company authorized the Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split as a ratio of one-for-eleven shares, which became effective on May 13, 2022. The Company's outstanding stock options were also adjusted to reflect the one-for-eleven reverse stock split of the Company's common stock. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The reverse stock split resulted in an adjustment to the Series X convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. All share and per share data in these condensed consolidated financial statements and related notes hereto have been retroactively adjusted to account for the effect of the reverse stock split for the periods ended December 31, 2022 and 2021, respectively.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The most significant accounting estimates inherent in the preparation of our the financial statements include estimates associated with fair value and classification of warrants, revenue recognition, allowance for doubtful accounts, credit losses, inventory reserves, accrued expenses, deferred license revenue, stock-based compensation, valuations and impairments of long-lived assets, and accounting for income taxes.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents excluding items held in Investments - Available for Sale as noted below. equivalents. Cash and cash equivalents include cash held in banks, money market mutual funds and unrestricted certificates of deposit. The Company's cash and cash equivalents exceeds the Federal Deposit Insurance Corporation insured limits. The Company has not experienced any credit losses for amounts in excess of insured limits. Currently, the Company does not reasonably believe a significant risk of credit loss exists.

Fair Value Measurement

The Company applies the guidance issued with ASC 820, *Fair Value Measurements*, which provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity ad and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Investments – Available for Sale

The Company determines the appropriate classification of its investments in equity and debt securities at the time of purchase and reevaluates such determination at each balance sheet date. Marketable equity securities that are bought and held principally for the purpose of selling them in the near term are reported at fair value, with unrealized gains and losses recognized in earnings. Marketable debt securities classified as available for sale securities are carried at fair market value, with the unrealized gains and losses, net of tax, included in the determination of comprehensive income (loss) and reported in stockholders' equity.

All of the Company's investments available-for-sale are subject to periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other than temporary.

Accounts Receivable

Accounts receivable are stated at invoice amounts. The carrying amount of trade accounts receivable is reduced by an allowance for doubtful accounts credit losses that reflects our best estimate of accounts that may not be collected. The Company reviews outstanding trade accounts receivable balances and based on its assessment of expected collections, the Company estimates the portion, if any, of the balance that may not be collected as well as a general valuation allowance for other accounts receivable based primarily on future forecasts, historical experience. loss information, and current economic conditions. All accounts or portions thereof deemed to be uncollectible are written off to the allowance for doubtful accounts. credit losses and credit loss expense.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined on the first-in first-out (FIFO) method. Inventory that is not expected to be converted to cash over the next year is classified as non-current. The Company's policy is to reserve for its drug product inventory that it determines is unlikely to be sold to, or if sold, unlikely to be utilized by its customers on or before its expiration date.

Property and Equipment

Property and equipment is recorded at cost and is depreciated using the straight-line method over the useful lives of the assets, which range from three to ten years. Expenditures for routine maintenance and repairs are expensed as incurred. Leasehold improvements are amortized using the straight-line method over the shorter of the useful lives or the related lease term.

Impairment of Long-lived Assets and Goodwill

Long-lived assets, such as property and equipment and definite-lived intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. Impairment losses on long-lived assets such as real estate and equipment, are recognized when events or changes in circumstances indicate that the undiscounted cash flows estimated to be generated by such assets are less than their carrying value and, accordingly, all or a portion of such carrying value may not be recoverable. Impairment losses are then measured by comparing the fair value of assets to their carrying amounts. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, there were no impairments of long-lived assets.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date.

Rockwell reviews goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit or the indefinite-lived intangible assets below their carrying values. Rockwell completed its annual impairment tests as of December 31, 2023 and 2022, and determined that no adjustment for impairment of goodwill or intangible assets was required during the years ended December 31, 2023 and 2022.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Intangible assets with definite indefinite useful lives are amortized over measured at their estimated useful lives. Intangible assets subject to amortization are reviewed for potential impairment whenever events or circumstances indicate that carrying amounts may not be recoverable. respective fair values as of the acquisition date. Goodwill was $0.9 million as of December 31, 2023 and December 31, 2022.

Definite-lived intangible assets consist of our customer list associated with the Evoqua asset acquisition and license fees related to the technology, intellectual property and marketing rights for Triferic covered under certain issued patents patents. Definite-lived intangible assets have been capitalized and are being amortized over the life of the related patents which is generally 17 years.

Deferred Revenue

In October 2014, the Company entered into a Distribution Agreement with Baxter, which had a term of 10 years and received an upfront fee of $20 million. The upfront fee was recorded as deferred revenue and is being recognized based on the proportion of product shipments to Baxter in each period, compared with total expected sales volume over

the term of the Distribution Agreement.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. Under the Distribution Agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products and provided customer service and order delivery to nearly all United States customers. Following the reacquisition of these rights, Rockwell will now be able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world.

Rockwell will pay Baxter a fee for the reacquisition of its distribution rights. This fee is payable in two equal installments on January 1, 2023 and April 1, 2023. To ensure that customer needs continue to be met after January 1, 2023, Baxter and Rockwell are working closely together to transition customers' purchases of Rockwell's hemodialysis concentrates from Baxter to Rockwell. The Company recognized revenue of approximately $2.5 million and $1.9 million for the years ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Distribution Agreement totaled $1.5 million and $5.2 million as of December 31, 2022 and 2021, respectively.

During the year ended December 31, 2016, the Company entered into a distribution agreement with Wanbang Biopharmaceuticals (the "Wanbang Agreement") and received an upfront fee of $4.0 million. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $0.2 million during each of the years ended December 31, 2022 and 2021. Deferred revenue related to the Wanbang Agreement totaled $2.3 million and $2.5 million as of December 31, 2022 and 2021, respectively.

In January 2020, the Company entered into license and supply agreements with Sun Pharma (the "Sun Agreements"), for the rights to commercialize Triferic (dialysate) in India. Under the terms of the Sun Agreements, Sun Pharma will be the exclusive development and commercialization partner for Triferic (dialysate) in India, and the Company will supply the product to Sun Pharma. In consideration for the license, the Company received an upfront fee of $0.1 million, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Sun Pharma, will guide the development and execution for Triferic (dialysate) in India. Sun Pharma will be responsible for all clinical and regulatory approval, as well as commercialization activities. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $10,000 for each of the years ended December 31, 2022 and 2021. Deferred revenue related to the Sun Pharma Agreement totaled $0.1 million as of December 31, 2022 and 2021, respectively.

In September 2020, the Company entered into a license and supply agreements with Jeil Pharmaceutical (the "Jeil Agreements"), for the rights to commercialize Triferic (dialysate) in South Korea. Under the terms of the Jeil Agreements, Jeil Pharmaceutical will be the exclusive development and commercialization partner for Triferic (dialysate) in South Korea, and the Company will supply the product to Jeil Pharmaceutical. In consideration for the license, the Company received an upfront fee of $0.4 million, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company andJeil Pharmaceutical, will guide the development and execution for Triferic (dialysate) in South Korea. Jeil Pharmaceutical will be responsible for all clinical and regulatory approval, as well as commercialization activities. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of $18,158 and $10,000 during the years ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Jeil Agreement totaled $0.4 million and $0.2 million as of December 31, 2022 and 2021, respectively.

In June 2021, the Company entered into license and supply agreements with Drogsan Pharmaceuticals (the "Drogsan Agreements"), for the rights to commercialize Triferic (dialysate) and Triferic AVNU in Turkey. Under the terms of the Drogsan Agreements, Drogsan Pharmaceuticals will be the exclusive commercialization partner for Triferic (dialysate) and Triferic AVNU in Turkey. In consideration for the license, the Company received an upfront fee of $0.15 million, and will be eligible for milestone payment and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Drogsan Pharmaceuticals, will guide the execution for Triferic (dialysate) and Triferic AVNU in Turkey. Drogsan Pharmaceuticals will be responsible for all regulatory approval and commercialization activities, and the Company will supply the product to Drogsan Pharmaceuticals for Turkey. The upfront fee will be recorded as deferred revenue and will be recognized as revenue based on the agreement term. The Company recognized revenue of $15,000 and $7,500 during the years ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Drogsan Agreements totaled approximately $0.1 million as of December 31, 2022 and 2021, respectively. their useful life.

Income Taxes

Rockwell accounts for income taxes in accordance with the provisions of ASC 740-10, *Income Taxes.* A current tax liability or asset is recognized for the estimated taxes payable or refundable on tax returns for the year. Deferred tax liabilities or assets are recognized for the estimated future tax effects of temporary differences between book and tax accounting and operating loss and tax credit carryforwards. A valuation allowance is established for deferred tax assets if the Company determine it to be more likely than not that the deferred tax asset will not be realized.

The effects of tax positions are generally recognized in the financial statements consistent with amounts reflected in returns filed, or expected to be filed, with taxing authorities. For tax positions that the Company considers to be uncertain,

current and deferred tax liabilities are recognized, or assets derecognized, when it is probable that an income tax liability has been incurred and the amount of the liability is reasonably estimable, or when it is probable that a tax benefit, such as a tax credit or loss carryforward, will be disallowed by a taxing authority. The amount of unrecognized tax benefits related to current tax positions is insignificant. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Research and Product Development

The Company recognizes research and product development expenses as incurred. The Company incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products aggregating approximately $3.1 million $1.1 million and $6.8 million $3.1 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Stock-Based Compensation

Service-Based Stock Unit Awards

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company recorded stock-based compensation expense on its options granted under the Company's equity compensation plans to its directors and officers, and its employees (See Note 12) 13).

Market and Performance-Based Stock Unit Awards

In addition to awards with service-based vesting conditions, the Company has granted performance share units with market and performance conditions, to certain of its executives. The fair value of awards with performance conditions are based on the fair value of the Company's common stock on the date of grant. The fair value of awards with market conditions are based on a Monte Carlo simulation model. Assumptions and estimates utilized in the calculation of the fair value of the market awards include the risk-free interest rate, dividend yield, average closing price, expected volatility based on the historical volatility of the Company, and the remaining period of the award.

The awards with performance conditions vest and result in issuance, at settlement, of common stock for each recipient based upon the recipient's continued employment with the Company through the settlement date of the award and the Company's achievement of specified milestones. The requisite service period of the awards with performance conditions is generally 1-2 years. In the case of awards with performance conditions, the Company recognizes stock-based compensation expense based on the grant date fair value of the award when achievement of the underlying performance-based targets become probable.

The awards with market conditions vest and result in the issuance of common stock based upon the recipient's continuing employment with the Company through the settlement date of the award related to the market capitalization criteria. The fair value related to the awards with market conditions is recorded as stock-based compensation expense over the period from date of grant to the settlement date regardless of whether the market capitalization is achieved.

Leases

The Company accounts for its leases under ASC 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheets as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use assets are amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line expense over the lease term. Variable lease expenses, if any, are recorded when incurred.

In calculating the right-of-use assets and lease liabilities, the Company elected the practical expedient to combine lease and non-lease components. Additionally, the Company excludes short-term leases having initial terms of 12 months or less as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

Commitments and Contingencies

In the normal course of business, the Company may become subject to loss contingencies, such as legal proceedings and claims arising out of its business, including government investigations. An accrual for a loss contingency is recognized when it is probable that an asset had been impaired or a liability had been incurred and the amount of loss can be reasonably estimated. The Company expenses legal costs associated with loss contingencies as they are incurred.

Restatement of Loss Per Share

Loss per share for the year ended December 31, 2022 was recalculated and restated and is presented on a comparable basis with the year ended December 31, 2023. In the first quarter of 2023, the Company determined it should have included pre-funded warrants issued in the second quarter of 2022 in the loss per share calculation in accordance with ASC 260-10-45-13, which treats shares of common stock exercisable for little to no consideration as included in the denominator of both the basic and diluted earnings per share calculations. While the Company has determined the impact of including the pre-funded warrants in the loss per share calculations does not have a material impact on previously issued financial statements, the Company has recalculated and restated amounts presented on a comparative and consistent basis with current period results. The table below summarizes previously reported and restated amounts on a comparative basis.

	Year Ended December 31, 2022
As Previously Reported:	
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted	$ (1.89)
Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted	9,866,844
As Restated:	
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted	$ (1.31)
Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted	14,304,512

Loss Per Share

ASC 260, *Earnings Per Share*, requires dual presentation of basic and diluted earnings per share ("EPS"), with a reconciliation of the numerator and denominator of the basic EPS computation to the numerator and denominator of the diluted EPS computation. Basic EPS excludes dilution. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issued common stock were exercised or converted into common stock or resulted in the issuance of common stock that are then shared in the earnings of the entity.

Basic net loss per share of common stock excludes dilution and is computed by dividing the net loss, less accretion of the Series X Preferred Stock, by the weighted average number of shares outstanding during the period. Diluted net loss per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that are then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. The Company has only incurred losses, therefore, basic and diluted net loss per share is the same. Securities that could

The Company's potentially dilute loss per share in dilutive securities include stock options, restricted stock awards and units, convertible preferred stock and warrants. These securities were excluded from the future that were not included in the computation computations of diluted net loss per share for the years ended December 31, 2023 and 2022, as the effect would be to reduce the net loss per share. The following table includes the potential shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of December 31,	
	2023	2022
Warrants to purchase common stock	3,793,388	10,196,268
Convertible Preferred Stock	1,363,636	1,363,636
Options to purchase common stock	1,328,621	1,206,905
Unvested restricted stock units	258,885	125,000
Unvested restricted stock awards	891	891
Total	6,745,421	12,892,700

Included within the weighted average shares of common stock outstanding for the year ended December 31, 2022 are 6,300,000 shares of common stock issuable upon the exercise of Pre-Funded Warrants (See Note 12), as the warrants were exercisable at any time for nominal consideration and, 2021 as such, the shares were considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders. There were no unexercised Pre-Funded Warrants as follows: of December 31, 2023.

	As of December 31,	
	2022	2021
Options to purchase common stock	1,206,905	528,591
Unvested restricted stock awards	891	7,118
Unvested restricted stock units	125,000	29,289
Convertible Preferred Stock	1,363,636	—
Common stock issuable under pre-funded warrants	6,300,000	—
Warrants to purchase common stock	10,196,268	2,402,442
Total	19,192,700	2,967,440

The following table presents the calculation of basic and diluted EPS:

	Years Ended December 31,

	2023	2022
Numerator:		
Net Loss	$ (8,439)	$ (18,679)
Accretion of Series X Preferred Stock	(150)	—
Net Loss Attributable to Common Stockholders	$ (8,589)	$ (18,679)
Denominator		
Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted	23,322,915	14,304,512
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted	$ (0.37)	$ (1.31)

Accumulated Other Comprehensive Income

Accumulated other comprehensive income includes all changes in equity during a period except those that resulted from investments by or distributions to the Company's stockholders. Accumulated other comprehensive income refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to stockholders' equity. Accumulated other comprehensive income consists of unrealized gains and losses on available-for-sale investment debt securities and foreign currency translation adjustments.

Adoption of Recent Accounting Pronouncements and New Accounting Pronouncements

The Company continually assesses any new accounting pronouncements to determine their applicability. When it is determined that a new accounting pronouncement affects the Company's financial reporting, the Company undertakes a study to determine the consequences of the change to its consolidated financial statements and assures that there are proper controls in place to ascertain that the Company's consolidated financial statements properly reflect the change.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, which introduced an impairment model that is based on expected credit losses, rather than incurred losses, to estimate credit losses on certain types of financial instruments (e.g., loan commitments). The expected credit losses should consider historical information, current information, and reasonable and supportable forecasts, including estimates of prepayments, over the contractual term. Financial instruments with similar risk characteristics may be grouped together when estimating expected credit losses. In addition, ASC 326 requires expected credit related losses for trade accounts receivable, as well as available-for-sale debt securities, which are to be recorded through an allowance for credit losses, while non-credit related losses will continue to be recognized through other comprehensive income. The Company adopted the new guidance, as of January 1, 2023, and it did not have a material impact on the consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting - Improvements to Reportable Segment Disclosures*, which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. The amendments in this ASU are effective

for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is in the process of determining the effect this ASU will have on the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which updates income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This ASU also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in this ASU are effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is in the process of determining the effect this ASU will have on the consolidated financial statements.

Note 4. Asset Acquisition

On July 10, 2023, the Company completed the Evoqua Asset Acquisition. At the Closing, the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to manufacturing and selling of hemodialysis concentrates products, all of which are manufactured under a contract manufacturing agreement with a third-party organization.

Pursuant to the Purchase Agreement, total consideration was $17.4 million, comprising a cash payment at Closing of $12.4 million (inclusive of transaction costs) and two $2.5 million deferred payments, the first to be paid on the one-year anniversary of the Closing, which is included as a current liability on the Company's consolidated balance sheet, and the second to be paid on the second anniversary of the Closing (collectively, the "deferred consideration").

The transaction was accounted for as an asset acquisition, as the acquired assets did not meet the definition of a business as defined by ASC 805, *Business Combinations*.

The purchase price was allocated, on a relative fair value basis, to the assets acquired at the July 10, 2023 acquisition date as follows (table in thousands):

Consideration		
Cash Payment	$	12,233
Deferred Consideration		5,000
Transaction Costs		128
Total Consideration	$	17,361
Assets Acquired		
Customer Relationships Intangible Asset	$	11,035
Equipment		5,093
Inventory		1,233
Total Assets Acquired	$	17,361

The fair value of the customer relationships intangible asset was determined using a multi-period excess earnings method, a form of the income approach, which incorporates the estimated future cash flows to be generated from the customer base. Key assumptions included discounted cash flows, estimated life cycle and customer attrition rates. Customer relationships are being amortized over a period of 20 years. Given the recency of the purchase of the equipment in which the assets were recorded at relative fair value, the Company determined the fair value of the equipment using a cost approach, which considered assumptions over the equipment's current replacement cost and useful life. Inventory was purchased directly from the contract manufacturer holding the inventory, which approximated fair value.

During the year ended December 31, 2023, the Company recorded amortization of its customer relationship intangible asset of $0.3 million, resulting in a net intangible asset of $10.8 million as of December 31, 2023.

Estimated future amortization expense on the Company's customer relationships intangible asset as of December 31, 2023 is as follows (table in thousands):

Year ended December 31:		
2024	$	552
2025		552
2026		552
2027		552
2028		552
Thereafter		7,999
Total	$	10,759

Note 4. 5. Investments - Available-for-Sale

Investments available-for-sale consisted of the following as of December 31, 2022 December 31, 2023 and 2021 2022 (tables in thousands):

	December 31, 2022				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities	Available-for-Sale Securities				
Bonds	Bonds	$11,315	$ 75	$ —	$ —	$11,390
Bonds						
Bonds						

	December 31, 2023				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value

	December 31, 2021				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value

	December 31, 2022					December 31, 2022				
	Amortized Cost					Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities	Available-for-Sale Securities									
Bonds	Bonds	$ 9,143	$ 1	$ —	$ 14	$9,158				
Bonds										
Bonds										

The fair value of investments available-for-sale are determined using quoted market prices from daily exchange-traded markets based on the closing price as of the balance sheet date and are classified as a Level 1 as described in Note 3, measurement under ASC 820, *Fair Value Measurement to our consolidated financial statements. Measurements*.

As of December 31, 2022 December 31, 2023 and 2021, the amortized cost and estimated fair value of 2022, our available-for-sale securities were due in one year or less.

Note 5. 6. Significant Market Segments and Customers

Rockwell operates in one market segment, the hemodialysis market, which involves the manufacture, sale and distribution of hemodialysis products to hemodialysis clinics, including pharmaceutical, dialysis concentrates, dialysis kits and other ancillary products used in the dialysis process.

One Rockwell's customer mix is diverse, with most customer sales concentrations under 10%, however, two customers, DaVita Inc. ("DaVita"), and Baxter, accounted for 46% approximately 47% and nil, respectively, of Rockwell's total net product sales in 2022 2023 and 47% 46% and 29%, respectively, of its total net product sales in 2021 (see Note 12). 2022. Rockwell's accounts receivable from DaVita and Baxter were $2.1 million and nil, respectively, as of December 31, 2023 and $1.9 million and $1.0 million $2.3 million, respectively, as of December 31, 2022 and 2021, respectively.

In October 2014, Rockwell entered into the Baxter Distribution Agreement, which was amended in June 2017 and March 2020, pursuant to which Baxter received exclusive distribution rights for . For additional information regarding the Company's concentrate products in the United States, a commitment by Rockwell to maintain a specified manufacturing capacity for contracts with DaVita and Baxter, a cap upon the net amount of reimbursable transportation expenses see Notes 3 and modified extension terms. Rockwell's domestic customer contracts for the supply of dialysis concentrate products that permitted assignment to Baxter without consent had been assigned to Baxter.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and has agreed to terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminate December 31, 2022. Rockwell agreed to provide certain services to a group of Baxter customers until March 31, 2023.Under the exclusive distribution agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products and provided customer service and order delivery to nearly all United States customers. Following the reacquisition of these rights, Rockwell will now be able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world. For 2022 and 2021, Rockwell's direct sales to Baxter aggregated approximately 29% and 26% of sales, respectively, and the Company had a receivable from Baxter of $2.3 million and $3.5 million as of December 31, 2022 and 2021, 10, respectively.

DaVita and the accounts previously administered by Baxter are is important to Rockwell's business, financial condition and results of operations. The loss of any significant accounts could have a material adverse effect on the Company's business, financial condition and results of operations. No other domestic customers current customer accounted for more than 10% its of sales in any of the last two years.

The majority of Rockwell's international sales in each of the last two years were sales to domestic distributors that were resold to end users outside the United States. Rockwell's sales to foreign customers and distributors accounted for approximately 9% and 10% of its total sales in 2022 each of 2023 and 2021, respectively. One international customer, Nipro Medical Corporation, accounted for 7% and 8% of its total sales for 2022 and 2021, respectively. 2022.

Note 6. Distribution Agreement

In October 2014, Rockwell entered into the Distribution Agreement with Baxter, pursuant to which Baxter became Rockwell's exclusive agent for commercializing its hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years ending October 2, 2024. Rockwell retained sales, marketing and distribution rights for its hemodialysis concentrate products for its international customers and in those countries in which it had an established commercial presence.

Pursuant to the Distribution Agreement, Rockwell received an upfront fee of $20 million in October 2014. The upfront fee was deferred and was recognized as revenue based on the proportion of product shipments to Baxter in each period to total expected sales volume over the term of the Distribution Agreement. Rockwell recognized revenue associated with the upfront fee totaling $2.5 million and $1.9 million for the years ended December 31, 2022, and 2021, respectively.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminate December 31, 2022. Rockwell agreed to provide certain services to a group of Baxter customers until March 31, 2023.Under the Distribution Agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products and provided customer service and order delivery to nearly all United States customers. Following the reacquisition of these rights, Rockwell is able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world.

Rockwell will pay Baxter a fee for the reacquisition of its distribution rights. This fee is payable in two equal installments on January 1, 2023 and April 1, 2023. To ensure that customer needs continue to be met after January 1, 2023, Baxter and Rockwell are working closely together to transition customers' purchases of Rockwell's hemodialysis concentrates from Baxter to Rockwell through March 31, 2023.

Note 7. Inventory

Components of inventory, net of reserves as of December 31, 2022 December 31, 2023 and 2021 2022 are as follows (table in thousands):

	December 31, 2022	December 31, 2021
December 31, 2023		December 31, 2023 December 31, 2022
Inventory - Current Portion		
Raw Materials		
Raw Materials		
Raw Materials Raw Materials	$ 4,627	$ 3,434
Work in Process Work in Process	351	201
Finished Goods Finished Goods	2,112	1,964
Total	$ 7,090	$ 5,599
Total Current Inventory		
Inventory - Long Term(1)		
Total Inventory		

As of December 31, 2022 and 2021, the Company classified $1.3 million and $1.5 million, respectively, of

1. Represents inventory as non-current all of which was related to Triferic raw materials. This Triferic inventory will is expected to be utilized for the Company's international partnerships. The In September 2022, the Company has discontinued its NDAs New Drug Applications ("NDAs") for Triferic (dialysate) and Triferic AVNU in the United States. As In 2023, the Company reserved $1.1 million of long-term inventory as a result Rockwell reserved an additional $606,000 representing all remaining API and finished goods related to Triferic. of the termination of the Wanbang development effort.

As of December 31, 2022 December 31, 2023 and 2021, 2022, Rockwell had total Concentrate inventory aggregating $5.8 million $5.9 million and $4.0 million $5.8 million, respectively, against which Rockwell had reserved $25,000 and $21,000, $25,000, respectively.

Note 8. Property and Equipment

As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company's property and equipment consisted of the following (table in thousands):

	2022	2021
December 31, 2023		December 31, 2023 December 31, 2022
Leasehold Improvements	Leasehold Improvements	$1,256 $1,204
Machinery and Equipment	Machinery and Equipment	5,922 5,864

Information Technology & Office Equipment	Information Technology & Office Equipment	1,845	1,845
Laboratory Equipment	Laboratory Equipment	807	676
		9,830	9,589
Accumulated Depreciation		(7,636)	(7,103)
		15,206	
		15,206	
		15,206	
Accumulated Depreciation and Amortization			
Net Property and Equipment	Net Property and Equipment	$2,194	$2,486

Depreciation and amortization expense during for the years ended December 31, 2022 December 31, 2023 and 2021 is as follows (table in thousands):

	2022	2021
Depreciation expense	$ 576	$ 668

2022 was $1.2 million and $0.6 million, respectively.

Note 9. Goodwill and Intangible Assets

Total goodwill was $0.9 million at each of December 31, 2022 and 2021. Rockwell completed its annual impairment tests as of December 31, 2022 and 2021, and determined that no adjustment for impairment of goodwill was required during the years ended December 31, 2022 and 2021.

Note 10. 9. Accrued Liabilities

Accrued liabilities as of December 31, 2022 December 31, 2023 and 2021 2022 consisted of the following (table in thousands):

	2022	2021
Accrued Research & Development Expense	$ 43	$ 366

December 31, 2023		December 31, 2023	December 31, 2022
Accrued Compensation and Benefits	Accrued Compensation and Benefits	2,568	1,791
Accrued Unvouchered Receipts	Accrued Unvouchered Receipts	585	796
Accrued Manufacturing Expense			
Accrued Workers Compensation	Accrued Workers Compensation	306	382
Accrued Research & Development Expense			
Other Accrued Liabilities	Other Accrued Liabilities	4,200	1,755
Total Accrued Liabilities	Total Accrued Liabilities	$7,702	$5,090

Note 10. Deferred License Revenue

In October 2014, the Company entered into an exclusive distribution agreement with Baxter, which had a term of 10 years, and received an upfront fee of $20 million. Under the exclusive distribution agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products and provided customer service and order delivery to nearly all U.S. customers. The upfront fee was recorded as deferred license revenue and was being recognized based on the proportion of product shipments to Baxter in each period, compared with total expected sales volume over the term of the distribution agreement. On November 9, 2022, Rockwell paid Baxter a fee, which was reflected as a reduction to revenue on the consolidated statements of operations, and was payable in two equal installments on January 1, 2023 and April 1, 2023, to reacquire its distribution rights to its hemodialysis concentrates products from Baxter and terminated the distribution agreement. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminated December 31, 2022. To ensure that customer needs continued to be met after January 1, 2023, Rockwell agreed to provide certain services to a group of Baxter's customers until March 31, 2023, and Baxter and Rockwell worked together to transition customers' purchases of Rockwell's hemodialysis concentrates through that date. Following the reacquisition of these rights, Rockwell is now unrestricted in its ability to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world. The Company recognized $2.5 million of revenue associated with the upfront fee during the year ended December 31, 2022, and recognized the remaining revenue of $1.5 million during the year ended December 31, 2023.

The remaining agreements with Sun Pharam, Jeil Pharmaceutical, and Drogan Pharmaceuticals comprise the current and long-term portions of deferred license revenue on the consolidated balance sheet as of December 31, 2023.

Note 11. Insurance Financing Note Payable

On July 3, 2022, the Company entered into a short-term note payable for $2.0 million, bearing interest at 5.40% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2022 and are paid on a straight-line amortization over 9 month nine months, and the final payment is was due on March 3, 2023. As of December 31, 2022, the Company's insurance note payable balance was $0.5 million and was paid fully in 2023.

On June 3, 2023, the Company entered into a new short-term note payable for $0.7 million, bearing interest at 9.59% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2023 and are paid on a straight-line amortization over nine months with the final payment due on March 3, 2024. As of December 31, 2023, the Company's insurance note payable balance was $0.2 million.

Note 12. Stockholders' Equity

Reverse Stock Split

On May 9, 2022, the stockholders of the Company authorized the Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split as a ratio of one-for-eleven shares, which became effective on May 13, 2022. The Company's outstanding stock options were also adjusted to reflect the one-for-eleven reverse stock split of the Company's common stock. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The reverse stock split resulted in an adjustment to the Series X convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. All share and per share data in these consolidated financial statements and related notes hereto have been retroactively adjusted to account for the effect of the reverse stock split.

Preferred Stock

On April 6, 2022, the Company and DaVita entered into the SPA, Securities Purchase Agreement ("SPA"), which provided for the issuance by the Company of up to $15 million of preferred stock to DaVita. On April 6, 2022, the Company issued 7,500 shares of Series X Preferred Stock for gross proceeds of $7.5 million. On June 2, 2022, the Company met the conditions for the Second Tranche through a Registered Direct and Private Placement Offering by raising $15 million in additional capital. As a result, on June 16, 2022, the

Company issued an additional 7,500 shares of the Series X Preferred Stock to DaVita for gross proceeds of $7.5 million (by virtue of this transaction, DaVita rises to the level of related party).

The Series X Preferred Stock was issued for a price of $1,000 per share (the "Face Amount"), subject to accretion at a rate of 1% per annum, compounded annually. If the Company's common stock trades above $22.00 for a period of 30 calendar days, the accretion will thereafter cease. As of December 31, 2023, the Series X Preferred Stock accreted a total of $0.2 million.

The Series X Convertible Preferred Stock is convertible to common stock at rate equal to the Face Amount, divided by a conversion price of $11.00 per share (subject to adjustment for future stock splits, reverse stock splits and similar recapitalization events). As a result, each share of Series X Preferred Stock will initially convert into approximately 91 shares of common stock. DaVita's right to convert to common stock is subject to a beneficial ownership limitation, which is initially set at 9.9% of the outstanding common stock, which limitation may be reset (not to exceed 19.9%) at DaVita's option and upon providing prior written notice to the Company. In addition, any debt financing is limited by the terms

of our Securities Purchase Agreement with DaVita. Specifically, until DaVita owns less than 50% of its investment, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $5 million or to refinance existing debt, unless DaVita consents.

Additionally, the Series X Preferred Stock has a deemed liquidation event and redemption clause which could be triggered if the sale of all or substantially all of the Company's assets relating to the Company's dialysis concentrates business line. Since the Series X Preferred Stock may be redeemed if certain assets are sold at the option of the holder, but is not mandatorily redeemable and the sale of the assets that would allow for redemption is within the control of the Company, the preferred stock has been classified as permanent equity and initially recognized at fair value of $15 million (the proceeds on the date of issuance) less issuance costs of $0.1 million, resulting in an initial value of $14.9 million. The Company will assess at each reporting period whether conditions have changed to now meet the mandatorily redemptive mandatory redemption definition which could trigger liability classification.

As of December 31, 2022 December 31, 2023 and 2021, 2022, there were 2,000,000 shares of preferred stock, $0.0001 par value per share, authorized and 15,000 and nil shares of preferred stock issued or outstanding, respectively. and outstanding.

Common Stock

As of December 31, 2022 December 31, 2023 and 2021, 2022, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 12,163,673 29,130,607 and 8,544,225 12,163,673 shares issued and outstanding, respectively.

As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company has reserved for issuance the following shares of common stock related to the potential exercise of employee stock options, unvested restricted stock, convertible preferred stock, pre-funded warrants and all other warrants: warrants (collectively, "common stock equivalents"):

	As of December 31,	
	2022	2021
Options to purchase common stock	1,206,905	528,591
Unvested restricted stock awards	891	7,118
Unvested restricted stock units	125,000	29,289
Convertible Preferred Stock	1,363,636	—
Common stock issuable under pre-funded warrants	6,300,000	—
Warrants to purchase common stock	10,196,268	2,402,442
Total	19,192,700	2,967,440

During the years ended December 31, 2022 and 2021, 2,756,377 and nil pre-funded warrants were exercised, respectively.

During the years ended December 31, 2022 and 2021, no vested employee stock options were exercised.

	As of December 31,	
Common stock and common stock equivalents:	2023	2022
Common stock	29,130,607	12,163,673
Common stock issuable upon exercise of pre-funded warrants	—	6,300,000
Common stock and pre-funded stock warrants	29,130,607	18,463,673
Warrants to Purchase Common Stock	3,793,388	10,196,268
Convertible Preferred Stock	1,363,636	1,363,636
Options to Purchase Common Stock	1,328,621	1,206,905
Unvested Restricted Stock Units	258,885	125,000
Unvested Restricted Stock Awards	891	891
Total	35,876,028	31,356,373

Controlled Equity Offering

On April 8, 2022, the Company entered into the Sales Agreement (the "ATM facility") with Cantor Fitzgerald & Co. as Agent, pursuant to which the Company may offer and sell from time to time up to $12,200,000 $12.2 million of shares of Company's common stock through the Agent (subject to restrictions under General Instruction I.B.6 to Form S-3).Agent.

In May 2022, the Company sold $7,500 7,500 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $15,135, at a weighted average selling price of approximately $2.02 per share. The Company paid $378 in commissions and offering fees related to the sale of shares of common stock.

During the quarter ended December 31, 2023, 640,944 shares were sold pursuant to the Sales Agreement for net proceeds of $1.1 million. Approximately $11.0 million remains available for sale under the ATM facility.

Registered Direct Offering

On May 30, 2022, the Company entered into the RD Registered Direct Purchase Agreement with the Purchaser, named therein, pursuant to which the Company agreed to issue issued and sell, sold, in a registered direct offering (the "Offering"), 844,613 shares of its common stock at price of 1.39 $1.39 per share, and pre-funded warrants to purchase up to an aggregate of 7,788,480 shares of common stock (the "Pre-Funded Warrants" and the shares of common stock underlying the Pre-Funded Warrants, the "Warrant Shares"). The purchase price of each Pre-Funded Warrant is was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each Pre-Funded Warrant is was $0.0001 per share.

A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrants to the extent the holder would own more than 9.99% of the Company's outstanding common stock immediately after exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrant. The RD Registered Direct Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties.

A total During the year ended December 31, 2023, all of the remaining 6,300,000 Pre-Funded Warrants remained outstanding as to purchase common stock were exercised at an exercise price of $0.0001 per share, which resulted in gross proceeds to the Company of $630. During the year ended December 31, 2022., 1,488,480 Pre-Funded Warrants to purchase common stock were exercised at an exercise price of $0.0001 per share, which resulted in gross proceeds to the Company of $149.

Private Placement

Also on May 30, 2022, concurrently concurrent with the Offering, the Company entered into the PIPE private investment in public equity "PIPE" Purchase Agreement relating to the offering and sale (the "Private Placement") of warrants to purchase up to a total of 9,900,990 shares of common stock (the "PIPE Warrants") and pre-funded warrants to purchase up to a total of 1,267,897 shares of common stock (the "PIPE "Pre-Funded PIPE Warrants"). Each warrant was sold at a price of $0.125 per underlying warrant share and is was exercisable at an exercise price of $1.39 per share. The warrants to purchase up to a total of 9,900,990 shares of common stock which expire in November 2027 contain certain valuation provisions on unexercised outstanding warrants if the Company were to experience a fundamental transaction as described in section 3(d) of the warrant agreement. The purchase price of each Pre-Funded PIPE Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each prefunded warrant is Pre-Funded PIPE Warrant was $0.0001 per share.

As of December 31, 2022, 9,900,990 PIPE Warrants and no all Pre-Funded PIPE Warrants remained outstanding.

In connection with the Private Placement, the Company entered into a Registration Rights Agreement with the Purchaser, dated as of June 2, 2022 (the "RRA"). Pursuant to the RRA, the Company was required to prepare and file a registration statement with the SEC no later than July 1, 2022, and to use its reasonable best efforts to have the registration statement declared effective as promptly as possible, subject to certain specified penalties if timely effectiveness is not achieved. The Company filed a registration statement on June 22, 2022 which became effective on July 5, 2022. were exercised.

The Offering and the Private Placement closed on June 2, 2022. The net proceeds to the Company from the Offering and the Private Placement were approximately $14.9 million, after deducting fees and expenses. Subject to certain ownership limitations, the PIPE Warrants are exercisable upon issuance.

The Company has accounted for the common stock related to the Offering and Private Placement as equity on the accompanying consolidated balance sheets sheet as of December 31, 2022. The amount allocated to common stock was $2.0 million. This allocation is equal to the total proceeds of $15.0 million $15.0 million less the amount allocated to Warrants of $12.9 million and is also net of the direct and incremental costs associated with the Offering and Private Placement of $0.1 million. The Black-Scholes pricing model was used to calculate the value of Warrants relating to the Offering and Private Placement.

On July 10, 2023, the Company entered into a letter agreement (the "Letter Agreement") with Armistice Capital Master Fund Ltd. ("Armistice"), which held a warrant (the "Prior Warrant") to purchase 9,900,990 shares of common stock of the Company (the "Common Stock") with an exercise price of $1.39 per share, offering Armistice the opportunity to exercise the Prior Warrant for cash, provided the Prior Warrant was exercised for cash on or prior to 5:00 P.M. Eastern Time on July 10, 2028 (the "End Date"). In addition, Armistice would receive a "reload" warrant (the "Reload Warrant") to purchase 3,750,000 shares of Common Stock with an exercise price of $5.13 per share, the closing price as reported by the Nasdaq Capital Market on July 7, 2023. The terms of the Reload Warrant and Letter Agreement provide for customary resale registration rights. The Reload Warrant may be exercised at all times prior to the 54 months month anniversary of its issuance date. The Prior Warrant and the Reload Warrant both provide that a holder (together with its affiliates) may not exercise any portion of the Prior Warrant or the Reload Warrant to the extent that the holder would own more than 9.99% of the Company's outstanding Common Stock immediately after exercise, as such percentage ownership is determined in accordance with the terms of such warrant. To the extent the exercise of the Prior Warrant would result in Armistice holding more than 9.99% of the Company's outstanding Common Stock, such shares of Common Stock in excess of 9.99% will be held in abeyance. The Letter Agreement amended the Prior Warrant to extend the expiration date thereof to one year following the original expiration date set forth therein.

Armistice exercised the Prior Warrant on July 10, 2023, and the Company received gross proceeds of approximately $13.8 million.

Note 13. Stock-Based Compensation

The Board of Directors adopted the Rockwell Medical, Inc., 2007 Long Term Incentive Plan ("2007 LTIP") on April 11, 2007. The 2007 LTIP expired on April 11, 2017 and no equity awards were granted under the 2007 LTIP following its expiration. There were 1,045,455 shares of common stock reserved for issuance under the 2007 LTIP. The Board of Directors adopted the 2018 Long-Term Incentive Plan ("2018 LTIP") on January 29, 2018 as a replacement for the Company's prior 2007 LTIP. Initially there were 300,000 shares of common stock reserved for issuance under the 2018 LTIP. On May 18, 2020, at the 2020 Annual Meeting, the Company's stockholders approved the amendment and restatement of the Rockwell Medical, Inc. 2018 Long Term Incentive Plan to increase Plan. As of December 31, 2023, the maximum number of shares of common stock issuable thereunder by 263,636 and on May 9,2022, at with respect to which awards may be issued under the 2021 Annual Meeting, the Company's stockholders approved the 2018 LTIP, as amended and restatement restated, was 2,618,182. As of December 31, 2023, the Rockwell Medical, Inc. 2018 Long Term Incentive Plan to increase the number of LTIP had 1,403,325 shares of common stock issuable thereunder by 454,546 shares bringing common stock reserve available for issuance up to 1,018,182 under the 2018 LTIP. grant. The Compensation Committee of the Board of Directors (the "Committee") is responsible for the administration of the 2007 LTIP and 2018 LTIP, including the grant of stock based awards and other financial incentives including performance based incentives to employees, non-employee directors and consultants.

The Company's standard stock option agreement agreements under the 2007 LTIP and 2018 LTIP allows allow for the payment of the exercise price of vested stock options either through cash remittance in exchange for newly issued shares, or through non-cash exchange of previously issued shares held by the recipient for at least six months in exchange for our newly issued shares. The 2007 LTIP and 2018 LTIP also allow allows for the retention of shares in payment of the exercise price and income tax withholding. The latter method results in no cash being received by the Company, but also results in a lower number of total shares being outstanding subsequently as a direct result of this exchange of shares. Shares returned to the Company in this manner would be are retired.

The Company recognized total stock-based compensation expense during the years ended December 31, 2022 December 31, 2023 and 2021 2022 as follows (table in thousands):

	Year Ended December 31,	
	2022	2021
Service based awards:		
Restricted stock units	$ 129	$ 344
Stock option awards	576	1,354
	$ 705	$1,697

	Year Ended December 31,	
	2023	2022
Service based awards:		
Restricted stock units	932	
Performance based awards:		
Restricted stock awards	$(390)	$ (390)
Stock option awards	—	(364)
	(390)	(754)
Total	$ 315	$ 943

Performance Based Restricted Stock Awards

A summary of the Company's performance based restricted stock awards during the years year ended December 31, 2022 and 2021 December 31, 2023 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2021	13,345	$ 62.70
Forfeited	(6,227)	$ 62.70
Unvested at December 31, 2021	7,118	62.70

Forfeited	(6,227)	—
Unvested at December 31, 2022	891	$ 62.70

Performance Based Restricted Stock Awards	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2023	891	$ 62.70
Unvested at December 31, 2023	891	$ 62.70

The fair value of Performance-based restricted stock awards are measured based on their fair value on the date of grant and amortized over the vesting period of 20 months. As of December 31, 2022, all unvested restricted stock awards were related to performance based awards. The 6,227 forfeited performance-based restricted stock awards were due to the termination of the Company's former Chief Development Officer on March 25, 2022. These forfeited awards reduced stock-based compensation expense by $0.4 million. Stock-based compensation expense of nil was recognized for each of the years ended December 31, 2022 and 2021. As of December 31, 2022 December 31, 2023, there is no unrecognized stock-based compensation expense related to performance-based restricted stock awards.

Service Based Restricted Stock Units

A summary of the Company's service based restricted stock units during the year ended December 31, 2022 and 2021 December 31, 2023 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2021	24,136	$ 28.60
Granted	28,186	9.90
Forfeited	(1,073)	52.91
Vested	(21,960)	24.97
Unvested at December 31, 2021	29,289	12.87
Granted	125,000	1.47
Forfeited	(5,774)	19.00
Vested	(23,515)	11.33
Unvested at December 31, 2022	125,000	$ 1.47

Service Based Restricted Stock Units	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2023	125,000	$ 1.47
Granted	313,065	$ 1.87
Forfeited	(54,180)	$ 1.37
Vested	(125,000)	$ 1.47
Unvested at December 31, 2023	258,885	$ 1.83

The fair value of service based restricted stock units are measured based on their fair value on the date of grant and amortized over the vesting period. The vesting periods range from 1-3 years. Stock-based compensation expense of $0.1 million was recognized for each of the years ended December 31, 2022 and 2021. As of December 31, 2022 December 31, 2023, the unrecognized stock-based compensation expense was $0.1 million $0.2 million which is expected to be recognized over the next 12 14 months.

Performance Based Restricted Stock Units

As of December 31, 2022, there were no issued or outstanding performance-based restricted stock units. As a result, there was no unrecognized stock-based compensation expense related to performance-based restricted stock units.

Service Based Stock Options Option Awards

The fair value of the service based stock options option awards granted for the years ended December 31, 2022 December 31, 2023 and 2021 2022 were based on the following assumptions:

	December 31,	
	2022	2021
Exercise price	$1.28 - $1.66	$5.94 - $5.94
Expected stock price volatility	76.2% - 78.5%	75.0% - 77.7%
Risk-free interest rate	1.97% - 3.44%	0.47% - 1.30%
Term (years)	5.5 - 6.0	5.5 - 6.0

	December 31,	
	2023	2022
Exercise price	$1.37 - $2.83	$1.28 - $1.66
Expected stock price volatility	81.6% - 81.8%	76.2% - 78.5%
Risk-free interest rate	3.41% - 4.84%	1.97% - 3.44%
Term (years)	4.0 - 6.0	5.5 - 6.0

A summary of the Company's service based stock option activity for the years year ended December 31, 2022 and 2021 December 31, 2023 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value *(in $1,000's)*
Outstanding at January 1, 2021	519,814	$ 50.05	6.6	$ —
Granted	177,014	9.68	6.0	—
Expired	(128,064)	(77.00)		
Forfeited	(40,173)	(24.42)	—	
Outstanding at December 31, 2021	528,591	$ 32.01	7.5	$ —
Granted	898,659	1.49	—	—
Expired	(96,199)	(78.06)	—	
Forfeited	(124,146)	(5.70)	—	
Outstanding at December 31, 2022	1,206,905	$ 28.31	8.9	$ —
Exercisable at December 31, 2022	243,088	$ 4.81	6.8	$ —

Service Based Stock Option Awards	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value *(in $1,000's)*
Outstanding at January 1, 2023				
Granted				
Granted				
Expired				
Forfeited				
Exercisable at December 31, 2023				

Service Based Stock Option Awards	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value *(in $1,000's)*
Outstanding at January 1, 2023				
Granted				
Expired				
Forfeited				
Exercisable at December 31, 2023				

Outstanding at December 31, 2023	
Outstanding at December 31, 2023	
Outstanding at December 31, 2023	
Exercisable at December 31, 2023	

The aggregate intrinsic value in the table above is calculated as the difference between the closing price of our the Company's common stock and the exercise price of the stock options that had strike prices below the closing price.

During the year ended December 31, 2022 and 2021, the The weighted average grant date fair value for service based stock options granted consisted of 898,659 option awards during the years ended December 31, 2023 and 177,014 options granted to employees, 2022 was $1.09 and $0.99, respectively.

As of December 31, 2022, 243,088 vested options were exercisable at a weighted average price of $28.31 per share.

During the year ended December 31, 2022 and 2021, stock-based compensation expense of $0.6 million and $1.4 million was recognized, respectively. As of December 31, 2022 December 31, 2023, total stock-based compensation expense related to 963,817 967,090 unvested options not yet recognized totaled approximately $0.9 million $0.7 million which is expected to be recognized over the next 3.7 3.0 years.

Performance Based Stock Options

As of December 31, 2022, there were no performance based stock options outstanding.

Note 14. License Agreements

Product License Agreements

The Company is a party to a Licensing Agreement between the Company and Charak, LLC ("Charak") dated January 7, 2002 (the "2002 Agreement") that grants the Company exclusive worldwide rights to certain patents and information related to our Triferic product. On October 7, 2018, the Company entered into a Master Services and IP Agreement (the "Charak MSA") with Charak and Dr. Ajay Gupta, a former Officer of the Company. Pursuant to the MSA, the parties entered into three additional agreements described below related to the license of certain soluble ferric pyrophosphate ("SFP") intellectual property owned by Charak, as well as the Employment Agreement (defined below). As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company has accrued $87,900 $85,400 and $86,400, $87,900, respectively, relating to certain IP reimbursement expenses and certain sublicense royalty fees as an accrued liability on the condensed consolidated balance sheet. sheets.

Pursuant to the Charak MSA, the aforementioned parties entered into an Amendment, dated as of October 7, 2018 (the "Charak Amendment"), to the 2002 Agreement, under which Charak granted the Company an exclusive, worldwide, non-transferable license to commercialize SFP for the treatment of patients with renal failure. The Charak Amendment amends the royalty payments due to Charak under the 2002 Agreement such that the Company is liable to pay Charak royalties on net sales by the Company of products developed under the license, which includes the Company's Triferic product, at a specified rate until December 31, 2021 and thereafter at a reduced rate from January 1, 2022 until February 1, 2034. Additionally, the Company shall is required to pay Charak a percentage of any sublicense income during the term of the agreement, which amount shall not cannot be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and be no less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

Also pursuant to the Charak MSA, the Company and Charak entered into a Commercialization and Technology License Agreement IV Triferic, dated as of October 7, 2018 (the "IV Agreement"), under which Charak granted the Company an exclusive, sublicensable, sub-licensable, royalty-bearing license to SFP for the purpose of commercializing certain intravenous-delivered products incorporating SFP for the treatment of iron disorders worldwide for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. The Company is was liable to pay Charak royalties on net sales by the Company of products developed under the license at a specified rate until December 31, 2021. From January 1, 2022 until February 1, 2034, the Company is liable to pay Charak a base royalty at a reduced rate on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the IV Agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and not be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

Also pursuant to the Charak MSA, the Company and Charak entered into a Technology License Agreement TPN Triferic, dated as of October 7, 2018 (the "TPN Agreement"), pursuant to which Charak granted the Company an exclusive, sublicensable, sub-licensable, royalty-bearing license to SFP for the purpose of commercializing worldwide certain TPN products incorporating SFP. The license grant under the TPN Agreement continues for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. During the term of the TPN Agreement, the Company is liable to pay Charak a base royalty on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the TPN Agreement, which amount shall not be less than a minimum royalty on net sales of the licensed products by the sublicensee

in jurisdictions where there exists a valid claim, on a country-by-country basis, and not be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

The potential milestone payments are not yet considered probable, and no milestone payments have been accrued at December 31, 2022 December 31, 2023.

Note 15. Commitments and Contingencies

Insurance

The Company evaluates various kinds of risk that it is exposed to in its business. In its evaluation of risk, the Company evaluates options and alternatives to mitigating such risks. For certain insurable risks, Rockwell may acquire insurance policies to protect against potential losses or to partially insure against certain risks. For the Company's subsidiary, Rockwell Transportation, Inc., Rockwell maintains a partially self-insured workers' compensation policy. Under the policy, its self-insurance retention is $350,000 per occurrence and $618,000 in aggregate coverage for the policy year ending June 1, 2024. The total amount at December 31, 2023 by which retention limits exceed the claims paid and accrued is approximately $535,000 for the policy year ending July 1, 2023. Estimated loss and additional future claims of approximately $254,000 have been reserved and accrued for the year ended December 31, 2023.

As of December 31, 2023, approximately $0.4 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2023, amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

Litigation

The Company may be involved in certain routine legal proceedings from time to time before various courts and governmental agencies. The Company cannot predict the final disposition of such proceedings. The Company regularly reviews legal matters and record provisions for claims considered probable of loss. The resolution of these pending proceedings is not expected to have a material effect on its operations or consolidated financial statements in the period in which they are resolved.

Note 16. Leases

Rockwell leases its production facilities and administrative offices as well as certain equipment used in its operations including leases on transportation equipment used in the delivery of its products. The lease terms range from monthly to seven years. Rockwell occupies a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2024. Rockwell also occupies two other manufacturing facilities, a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2025, and a 57,000 square foot facility in Greer, South Carolina under a lease expiring February 2026. In addition, Rockwell occupies 4,100 square feet of office space in Hackensack, New Jersey under a lease expiring on October 31, 2024. This lease was subleased on December 15, 2021 with an expiration date of October 31, 2024.

The following summarizes quantitative information about the Company's operating and finance leases (dollars in thousands):

		For the year ended December 31, 2022	For the year ended December 31, 2021
		For the year ended December 31, 2023	
		For the year ended December 31, 2023	
		For the year ended December 31, 2023	
Operating leases			
Operating leases			
Operating leases	**Operating leases**		
Operating lease cost	Operating lease cost	$ 1,710	$ 1,793
Operating lease cost			
Operating lease cost			
Variable lease cost			
Variable lease cost			
Variable lease cost	Variable lease cost	388	373
Operating lease expense	Operating lease expense	2,098	2,166
Operating lease expense			

Operating lease expense					
Finance leases					
Finance leases					
Finance leases	**Finance leases**				
Amortization of right-of-use assets	Amortization of right-of-use assets		565		313
Amortization of right-of-use assets					
Amortization of right-of-use assets					
Interest on lease obligations					
Interest on lease obligations					
Interest on lease obligations	Interest on lease obligations		179		99
Finance lease expense	Finance lease expense		744		412
Finance lease expense					
Finance lease expense					
Short-term lease rent expense	Short-term lease rent expense		17		17
Short-term lease rent expense					
Short-term lease rent expense					
Total rent expense					
Total rent expense					
Total rent expense	Total rent expense	$	2,859	$	2,595
Other information	**Other information**				
Other information					
Other information					
Operating cash flows from operating leases					
Operating cash flows from operating leases					
Operating cash flows from operating leases	Operating cash flows from operating leases	$	1,772	$	1,772
Operating cash flows from finance leases	Operating cash flows from finance leases	$	179	$	99
Operating cash flows from finance leases					
Operating cash flows from finance leases					
Financing cash flows from finance leases	Financing cash flows from finance leases	$	482	$	255
Right of use assets exchanged for operating lease liabilities		$	768	$	4,217
Right of use assets exchanged for finance lease liabilities		$	—	$	2,431
Financing cash flows from finance leases					
Financing cash flows from finance leases					
Right of use assets obtained in exchange for operating lease liabilities					
Right of use assets obtained in exchange for operating lease liabilities					
Right of use assets obtained in exchange for operating lease liabilities					
Weighted-average remaining lease term - operating leases					
Weighted-average remaining lease term - operating leases					

Weighted-average remaining lease term - operating leases	Weighted-average remaining lease term - operating leases		3.0		3.5	
Weighted-average remaining lease term – finance leases	Weighted-average remaining lease term – finance leases		4.4		5.4	
Weighted-average remaining lease term – finance leases						
Weighted-average remaining lease term – finance leases						
Weighted-average discount rate - operating leases						
Weighted-average discount rate - operating leases						
Weighted-average discount rate - operating leases	Weighted-average discount rate - operating leases	6.4	%	6.3	%	
Weighted-average discount rate – finance leases	Weighted-average discount rate – finance leases	6.4	%	6.4	%	
Weighted-average discount rate – finance leases						
Weighted-average discount rate – finance leases						

Future minimum rental payments under operating and finance lease agreements are as follows (table in thousands):

	Operating	Finance
Year ending December 31, 2023	$ 1,672	$ 668
Year ending December 31, 2024	1,405	672
Year ending December 31, 2025	937	676
Year Ended December 31, 2026	310	666
Year Ended December 31, 2027	121	311
Remaining future payments	—	—
Total	4,445	2,993
Less present value discount	$ (380)	$ (384)
Operating and Finance lease liabilities.	$ 4,065	$ 2,609

Insurance

The Company evaluates various kinds of risk that it is exposed to in its business. In its evaluation of risk, the Company evaluates options and alternatives to mitigating such risks. For certain insurable risks, Rockwell may acquire insurance policies to protect against potential losses or to partially insure against certain risks. For the Company's subsidiary, Rockwell Transportation, Inc., Rockwell maintains a partially self-insured workers' compensation policy. Under the policy, its self-insurance retention is $350,000 per occurrence and $621,000 in aggregate coverage for the policy year ending July 1, 2023. The total amount at December 31, 2022 by which retention limits exceed the claims paid and accrued is approximately $534,000 for the policy year ending July 1, 2023. Estimated loss and additional future claims of approximately $306,000 have been reserved and accrued for the year ended December 31, 2022.

As of December 31, 2022, approximately $0.4 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2022, amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

Purchase Obligations

Rockwell has contracts for anticipated future obligations through December 31, 2022 of approximately $31.0 million, which include $29.4 million for concentrate manufacturing and $1.6 million in ancillary supplies.

Litigation

SEC Investigation

As a follow up to certain prior inquiries, the Company received a subpoena from the SEC during the Company's quarter ended September 30, 2018 requesting, among other things, certain information and documents relating to the status of the Company's request to the Centers for Medicare & Medicaid Services for separate reimbursement status for

Triferic (dialysate), the Company's reserving methodology for expiring Triferic inventory, and the basis for the Board's termination of the former Chief Executive Officer, Robert Chioini, and former Chief Financial Officer, Thomas Klema, in 2018. On January 31, 2022, the Company received a letter from the United States Securities and Exchange Commission (the "Commission") concluding it's investigation and stating that it does not intend to recommend an enforcement action by the Commission against the Company.

	Operating	Finance
Year ending December 31, 2024	$ 1,511	$ 672
Year ending December 31, 2025	1,021	676
Year Ended December 31, 2026	362	666
Year Ended December 31, 2027	129	311
Year Ended December 31, 2028	2	—
Total	3,025	2,325
Less present value discount	(211)	(237)
Operating and Finance lease liabilities.	$ 2,814	$ 2,088

Note 16. 17. Loan and Security Agreement

On March 16, 2020, Rockwell and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), as collateral agent and the lenders party thereto, pursuant to which Innovatus, as a lender, agreed to make certain term loans to the Company in the aggregate principal amount of up to $35.0 million (the "Term Loans"). Funding of the first $22.5 million tranche was completed on March 16, 2020. The Company is no longer eligible to draw on a second tranche of $5.0 million, additional tranches, which was were tied to the achievement of certain milestones by a specific date. The Company may be eligible to draw on a third tranche of $7.5 million upon the achievement of certain additional milestones, including the achievement of certain Triferic sales thresholds. milestones. Net draw down proceeds were $21.2 million with closing costs of $1.3 million. The Company also owes an additional fee equal to 4.375% of the funded amount of the Term Loans, or $1.0 million (such additional fee, the "Final Fee") at maturity. The Company is accreting up to this Final Fee premium with a charge against interest expense on the accompanying consolidated statements of operations.

In connection with each funding of the Term Loans, the Company was required to issue to Innovatus a warrant (the "Warrants") to purchase a number of shares of the Company's common stock equal to 3.5% of the principal amount of the relevant Term Loan funded divided by the exercise price. In connection with the first tranche of the Term Loans, the Company issued a Warrant to Innovatus, exercisable for, after considering the impact of the reverse stock split as further described in Note 12, an aggregate of 43,388 shares of the Company's common stock at an exercise price of $18.15 per share. The Warrant may be exercised on a cashless basis and is immediately exercisable through the seventh anniversary of the applicable funding date. The number of shares of common stock for which the Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant. The Company evaluated the warrant under ASC 470, *Debt*, and recognized an additional debt discount of approximately $0.5 million based on the relative fair value of the base instruments and warrants. The Company calculated the fair value of the warrant using the Black-Scholes model.

The Company is entitled Term Loan was scheduled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Term Loans will mature on March 16, 2025, and will bear interest at the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75%, plus 4.00% with an initial interest rate of 8.75% per annum and an effective interest rate of 10.90% 12.50% as of December 31, 2023. The Company has had the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. For the year ended December 31, 2022 December 31, 2023, interest expense amounted to $1.5 million $1.2 million.

The Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. Proceeds will be used for working capital purposes. The Loan Agreement and contains customary representations and warranties and covenants, subject to customary carve outs, and includes initially included financial covenants related to liquidity and trailing twelve months sales of Triferic, with Triferic. There can be no assurances that the latter beginning with the period ending December 31, 2022. We cannot assure you that we Company can maintain compliance with the covenants under our the Loan Agreement, which may result in an event of default. Our The Company's ability to comply with these covenants may be adversely affected by events beyond our its control. For example, the Loan Agreement contains certain financial covenants relating to sales and, as a result of the ongoing COVID-19 pandemic geopolitical and its effect on our sales activities, among other factors, we the Company may not be able to satisfy such covenants in the future. If the Company is unable to comply with the covenants under the Loan Agreement, it would pursue all available cure options in order to regain compliance. The Company previously failed to satisfy a revenue covenant for the period ended December 31, 2020 and then subsequently agreed to an appropriate remedy during the applicable cure period. However, the Company may not be able to mutually agree with Innovatus on appropriate remedies to cure a future breach of a covenant, which could give rise to an event of default. If the Company is unable to avoid an event of default, any required repayments could have an adverse effect on its liquidity. The financial statements for December 31, 2022 December 31, 2023 have been prepared with the assumption that the Company will be able to agree to an appropriate remedy during the applicable cure period for any future breaches of operating covenants.

In connection with each funding of the Term Loans, the Company is required to issue to Innovatus a warrant (the "Warrants") to purchase a number of shares of the Company's common stock equal to 3.5% of the principal amount of the relevant Term Loan funded divided by the exercise price, which will be based on the lower of (i) the volume weighted average closing price of the Company's stock for the 5-trading day period ending on the last trading day immediately preceding the execution of the Loan Agreement or (ii) the closing price on the last trading day immediately preceding the execution of the Loan Agreement (or for the second and third tranches only at the lower of (i) $1.65 per share or (ii) the volume weighted average closing price of the Company's stock for the 5-trading day period ending on the last trading day immediately preceding the relevant Term Loan funding). The Warrants may be exercised on a cashless basis and are immediately exercisable through the seventh anniversary of the applicable funding date. The number of shares of common stock for which each Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant. In connection with the first tranche of the Term Loans, the Company issued a Warrant to Innovatus, exercisable for an aggregate of 477,273 shares of the Company's common stock at an exercise price of $1.65 per share. The Company evaluated the warrant under ASC 470, Debt, and recognized an additional debt discount of approximately $0.5 million based on the relative fair value of the base instruments and warrants. The Company calculated the fair value of the warrant using the Black-Scholes model.

In September 2021, the Company entered into an amendment to the Loan Agreement in which the Company, in exchange for Innovatus lowering the sales covenants, agreed to (i) prepay an aggregate principal amount of $7.5 million in ten installments commencing on December 1, 2021; (ii) pay an additional prepayment premium of 5% on prepaid amounts if the Company elects to prepay all outstanding term loans on or before September 24, 2023 and (iii) maintain minimum liquidity of no less than $5.0 million if the aggregate principal amount of term loans is greater than $15.0 million pursuant to the liquidity covenant in the Loan Agreement.

On November 10, 2022, the Company entered into a Second Amendment to the Loan and Security Agreement (the "Second Amendment") dated as of November 14, 2022 with Innovatus. Pursuant to the Second Amendment, the Company (i) prepaid an additional aggregate principal amount of $5.0 million in Term Loans in one installment on November 14, 2022; and (ii) shall pay paid interest only payments until September 2023, at which time will resume it resumed scheduled debt payments. As The financial covenant related to the sales of December 31, 2022 Triferic was replaced with the trailing 6 months revenue of our concentrates products. The Company's ability to comply with the covenants under the Loan Agreement may be adversely affected by events beyond its control. If the Company is unable to comply with the covenants under the Loan Agreement, it would pursue all available cure options in order to regain compliance. However, the Company may not be able to mutually agree with Innovatus on appropriate remedies to cure a future breach of a covenant, which could give rise to an event of default. However, as of December 31, 2023, the Company was in compliance with its financial covenants under the Loan Agreement.

On January 2, 2024, the Company's Loan Agreement was amended to include, among other things, an interest-only period for 30 months, or up to 36 months if certain conditions are met, and reporting covenants. extend the maturity date to January 1, 2029. (See Note 19 for further detail).

As of December 31, 2022 December 31, 2023, the outstanding balance of the Term Loan was $9.2 million $8.3 million, net of unamortized issuance costs, and discount of $0.8 million. $0.4 million, and including $0.7 million of premium accretion.

The following table reflects the schedule of principal payments on the Term Loan as of December 31, 2022 December 31, 2023 after giving effect to the January 2, 2024 amendment (in thousands):

Year	Year	Principal Payments	Year	Principal Payments
2023		2,000		
2024	2024	6,000		
2025	2025	2,000		
		$ 10,000		
2026				
2027				
2028				
2029				
Total				

Note 17. 18. Income Taxes

A reconciliation of income tax expense at the statutory rate to income tax expense at our effective tax rate is as follows (dollars in thousands):

	2022	2021
Tax Expense (Benefit) Computed at 22.68% and 22.62% of Pretax Income (Loss)	$(4,361)	$(6,744)

Year Ended December 31,		Year Ended December 31,	
2023		2023	2022
Tax Benefit Computed of Pretax Loss			
Changes in Tax Laws	Changes in Tax Laws	—	—
Foreign Income Tax Expense	Foreign Income Tax Expense	—	—
Effect of Change in Valuation Allowance	Effect of Change in Valuation Allowance	4,361	6,744

Total Income Tax Expense	Total Income Tax Expense	$ —	$ —

The details of the net deferred tax asset are as follows (dollars in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net Operating Loss Carryforward	$ 70,686	$ 66,895
Stock Based Compensation	7,792	7,726
Deferred Revenue	983	1,846
General Business Credit	6,872	6,872
Accrued Expenses	605	174
Inventories	234	88
Book over Tax Depreciation	—	6
Research & Experimental Expenses	371	—
Other Deferred Tax Assets	1,274	865
Total Deferred Tax Assets	88,817	84,472
Deferred Tax Liabilities:		
Book over Tax Depreciation	8	—
Goodwill & Intangible Assets	224	183
Prepaid Expenses	316	381
Total Deferred Tax Liabilities	548	564
Subtotal	88,269	83,908
Valuation Allowance	(88,269)	(83,908)
Net Deferred Tax Asset	$ —	$ —

The Tax Cuts and Jobs Act of 2017 ("TCJA") impacted how net operating losses are utilized.The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") temporarily suspends the TCJA limitation, allowing a net operating loss carryforward to fully offset taxable income in tax years beginning before January 1, 2021.The CARES Act also temporarily reinstated a carryback period for all net operating losses generated in years beginning after December 31, 2017 and before January 1, 2021.The carryback period for those years is five years under the CARES Act.

	December 31,	
	2023	2022
Deferred tax assets:		
Net Operating Loss Carryforward	$ 72,612	$ 70,686
Stock Based Compensation	7,856	7,792
General Business Credit	6,872	6,872
Research & Experimental Expenses	459	371
Inventories	398	234
Accrued Expenses	144	605
Deferred License Revenue	118	983
Other Deferred Tax Assets	1,989	1,274
Total Deferred Tax Assets	90,448	88,817
Deferred Tax Liabilities:		
Goodwill & Intangible Assets	259	224
Prepaid Expenses	181	316
Book over Tax Depreciation	35	8

Total Deferred Tax Liabilities	475	548
Subtotal	89,973	88,269
Valuation Allowance	(89,973)	(88,269)
Net Deferred Tax Asset	$ —	$ —

Deferred tax assets result primarily from net operating loss carryforwards. For federal tax purposes, we have net operating loss carryforwards of approximately $311.6 million $321.4 million of which approximately $165.3 million $164.7 million began expiring in 2023 and will continue to expire between 2023 and through 2038.

In assessing the potential for realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company recognized no income tax expense or benefit for the years ended December 31, 2022, December 31, 2023 and 2021. 2022. Considered together with the Company's limited history of operating income and its net losses in 2022 2023 and 2021, 2022, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2022 December 31, 2023 and 2021. The portion of the valuation allowance resulting from excess tax benefits on share based compensation that would be credited directly to contributed capital if recognized in subsequent periods is $3.9 million. 2022.

Rockwell accounts for its uncertain tax positions in accordance with ASC 740-10, *Income Taxes* and the amount of unrecognized tax benefits related to tax positions is not significant at December 31, 2022 December 31, 2023 and 2021. 2022. The Company has not been under tax examination in any jurisdiction for the years ended December 31, 2022 December 31, 2023 and 2021. Tax examination years 2022. A recent IRC Section 382 study has not been performed, which could limit the value of 2018 to 2021 remain open. the Company's net operating losses.

Note 18. 19. Subsequent Events

Third Amendment to Loan Agreement

On January 25, 2023 January 2, 2024, 389,000 the Company and Rockwell Transportation, Inc. entered into the Third Amendment to and Restatement of Pre-Funded Warrants the Loan and Security Agreement (the "A&R Loan Agreement") with Innovatus, dated January 1, 2024 (the "A&R Effective Date"). The A&R Loan Agreement provides for the continuation of term loans initially borrowed under the Loan Agreement amounting to $8.0 million as of the A&R Effective Date. The Company will make interest-only payments on the Term Loans for 30 months, or up to 36 months if certain conditions are met. The Term Loans will mature on the fifth anniversary of the A&R Effective Date, unless earlier repaid. The Term Loans will bear interest at the greater of (i) Prime Rate (as defined in the A&R Loan Agreement) and (ii) 7.50%, plus 3.50%. At the Company's option, 2.00% of the interest due on any applicable interest payment date during the interest-only period may be paid in-kind by adding such amount to the then outstanding principal balance of the Term Loans.

The Term Loans may be voluntarily prepaid in full (but not partially) at any time, upon at least seven business days' prior notice. In connection with any voluntary prepayment or satisfaction of the Term Loans prior to the maturity date

(including any acceleration), the Company will pay all accrued and unpaid interest and all other amounts due in connection with the Term Loans, together with (x) a prepayment fee (the "Prepayment Fee") equal to: (i) 6.0% of the principal amount of the Term Loans prepaid if the payment is made before the first anniversary of the A&R Effective Date; (ii) 2.0% of the principal amount of the Term Loans prepaid if the payment is made after the first anniversary of the A&R Effective Date but on or before the second anniversary of the A&R Effective Date; (iii) 1.0% of the principal amount of the Term Loans prepaid if the payment is made after the second anniversary of the A&R Effective Date but on or before the third anniversary of the A&R Effective Date; or (iv) 0% of the principal amount of the Term Loans prepaid if the payment is made after the third anniversary of the A&R Effective Date through maturity, and (y) an additional fee equal to 4.375% of the funded amount of the Term Loans Final Fee. The Term Loans will be mandatorily prepaid upon a change in control of the Company, or upon any early termination/acceleration of the Term Loans. In the event of a mandatory prepayment of the Term Loans, the Company shall be required to pay the Prepayment Fee (if applicable), as well as the Final Fee. The Final Fee shall be due and payable at maturity if it has not previously been paid in full in connection with a prepayment of the Term Loans.

The A&R Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. Proceeds were exercised. used for working capital purposes. The A&R Loan Agreement contains customary representations and warranties and affirmative and negative covenants, subject to exceptions as described in the A&R Loan Agreement. The A&R Loan Agreement includes a financial covenant that requires actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 85.0% of the projections for the same period and, beginning with the quarter ending September 30, 2024, actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 80.0% of the projections for the same period. The A&R Loan Agreement also includes a financial covenant that requires that the Company to maintain minimum liquidity of the greater of (x) the Company's three-month cash burn or (y) the sum of $1.5 million and the aggregate amount of finance lease payments required to be made during the succeeding 12 months (or during a continuing event of default, the aggregate amount of finance lease payments required to be made during the entire term of such capital leases).

In connection with the execution of the A&R Loan Agreement, on January 2, 2024, the Company issued to Innovatus a warrant to purchase 191,096 shares of the Company's common stock with an exercise price of each Pre-Funded Warrant is $0.0001 $1.83 per share. (See Note 12 The warrant may be exercised on a cashless basis, and is immediately exercisable through the January 2, 2029. The number of shares of common stock for more detail on which the Pre-Funded Warrants). warrant is exercisable and the exercise price are subject to certain proportional adjustments as set forth in the warrant.

Exhibit 10.30

Employment Agreement

DISTRIBUTION TERMINATION AND ACQUISITION AGREEMENT

This Distribution Termination and Acquisition Employment Agreement (the "*Agreement*") is entered into the date both Parties have signed this agreement, and is between Baxter Healthcare Corporation, a Delaware corporation ("**Baxter**" or made as of July 21, 2021 (the "*Distributor Effective Date*"), by and between Rockwell Medical, Inc., a Delaware corporation ("**Rockwell**" or (the "*Company*"), and Megan C. Timmins ("*Executive*"), subject to the terms and conditions defined in this Agreement.

WHEREAS, the Company and Executive desire the Executive be employed by the Company to act as the Company's SVP, General Counsel and Secretary and member of the Company's Senior Leadership Team, subject to the terms and conditions set forth in this Agreement and such policies and procedures as the Company may from time to time implement and that are provided to the Executive;

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and Executive hereby agree as follows:

1. Certain Definitions. Baxter Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Executive's Duties and Rockwell are sometimes individually Obligations.

(a) Duties; Start Date. Executive shall serve as the Company's SVP, General Counsel and Secretary effective on August 16, 2021, or such other mutually agreeable date (such date being referred to herein as a "**Party**" and collectively as the "*Parties Commencement Date*"). Capitalized terms that are used but not defined herein Executive shall report to the President and Chief Executive Officer of the Company ("*CEO*"). Executive shall have those duties and responsibilities customarily associated with the meanings given position of SVP, General Counsel and Secretary of a public-traded company of the size and nature of the Company, and such other additional duties and responsibilities consistent with Executive's position as may, from time to them in time, be assigned to Executive by the Distribution Agreement.

Recitals

A. Baxter and Rockwell entered into an Exclusive Distribution Agreement dated as CEO or the board of October 2, 2014, as amended, with an initial term expiring October 2, 2024 directors of the Company (the "*Distribution Board*").

(b) At-Will Employment. Executive's employment shall be on an at-will basis, meaning that either party may terminate this employment arrangement at any time and without cause. The term of this Agreement shall be from the Effective Date through the applicable date of termination (the "*Term*"). On the date of termination of employment, Executive acknowledges that she shall immediately be deemed to have resigned all employment and related job duties and responsibilities with the Company, including, without limitation, any positions on any Company committees or other similar positions of an affiliated company. Executive agrees to sign all reasonable documentation evidencing the foregoing as may be presented to Executive for signature by the Company.

(c) Confidential Information and Inventions Matters. In consideration of the covenants contained herein, Executive has executed and agrees to be bound by the Company's form of Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-Competition Agreement (the "*Confidentiality Agreement*"), in the form attached to this Agreement as Exhibit B. Executive shall comply in all material respects at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information. In the event that Executive breaches any provisions of this Agreement or the Confidentiality Agreement, then, in addition to any other rights

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which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to seek injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of this Agreement or the Confidentiality Agreement, Executive shall not assert as a defense that there is an adequate remedy at law, nor shall the Company be prevented from seeking any other remedies which may be available.

(d) Location of Office. Executive's primary office location will be her home office, which is currently in Newton Square, Pennsylvania.

3. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During Executive's employment with the Company, Executive shall devote substantially all of Executive's business time, attention and efforts to the proper performance of Executive's duties and obligations hereunder.

(b) No Other Employment. During Executive's employment with the Company, Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the CEO; *provided, however*, that it shall not be a violation or breach of this Agreement for Executive to (i) accept speaking or presentation engagements in exchange for honoraria; (ii) serve on boards of charitable organizations or participate in charitable, educational, religious or civic activities; (iii) attend to her and her family's personal affairs; or (iv) own no more than three percent (3%) of the outstanding equity securities of a corporation whose stock is listed on a national stock exchange, so long as such activities are not adverse to the Company's interests and do not materially interfere with the performance of Executive's duties hereunder.

4. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to Executive base annual compensation ("*Base Salary*") of $400,000 (with $15,384.62 paid to Executive on a bi- weekly basis), payable in accordance with the Company's regular payroll practices and less all required withholdings benefits as hereinafter set forth in this Section 4. Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the Compensation Committee of the Company's Board. Executive's Base Salary may not be subject to reduction from the level set forth above or such later increased level as determined by the Compensation Committee, unless pursuant to which Rockwell a salary reduction program of general application to senior executives of the Company, provided that, unless agreed to develop, manufacture in writing by Executive, the percentage reduction of Executive's Base Salary shall not be greater than the percentage reduction applied to any other senior executive of the Company.

(i) Annual Bonus. During the Term and sell Rockwell Products (as defined commencing in 2021, Executive shall be eligible for year-end bonuses, which shall be paid in cash (any such bonus an "*Annual Bonus*"),

in a target amount equal to 40% of Executive's Base Salary, as then in effect (the "*Target Bonus*"), as may be awarded pursuant to any annual executive bonus plan and related performance goals established by the CEO and the achievement of corporate goals approved solely at the discretion of the Compensation Committee of the Board. Any such Annual Bonus shall contain such rights and features as are typically afforded to other senior executives of the Company. To be eligible to receive an Annual Bonus, the Executive must be employed by the Company on the date such bonuses are paid. Executive's Annual Bonus shall be pro-rated for 2021, in accordance with Executive's Commencement Date.

(b) Long-Term Incentive Grants. As of the Commencement Date, the Executive will eligible to participate in the Distribution Agreement) Company's Amended and Baxter agreed to market, sell, and distribute Rockwell Products pursuant Restated 2018 Long Term Incentive Plan (the "*Plan*"). Such awards will be subject in all respects to the terms and conditions of the Distribution Agreement; Plan and the forms of award agreement adopted by the Board for use thereunder.

B. (i) Rockwell wishes Initial Option Grant. On the Commencement Date, as a material inducement to reacquire distribution rights for Rockwell Products Executive agreeing to join the Company, Executive shall be awarded an option to purchase up to 350,000 shares of common stock (the "*Option*"). The Option will have an exercise price equal to the closing price of the Company's common stock on the Commencement Date and terminate will vest and become exercisable as follows: (1) 175,000 will vest and become exercisable on the Distribution Agreement second anniversary of the Commencement Date; and commence selling Products directly (2) the remaining 175,000 will vest and become exercisable on the fourth anniversary of the Commencement Date, subject to customers; the Executive's continued service through each applicable vesting date. The terms and conditions of the Option will also be subject to the applicable award agreement, provided that the Option shall be issued outside of the Company's shareholder-approved equity incentive plans, as permitted under applicable Nasdaq rules.

C. (ii) Baxter and Rockwell want Annual Equity Grants. During the Term, Executive shall be eligible to work together to help maintain reasonable continuity of supply of Product to customers. receive annual long-term incentive grants consistent with similar practices for the Company's senior executives, which may be paid in either cash or equity, or both (any such grants a "

In consideration *Long- Term Incentive Grant*"), as may be awarded solely at the discretion of the undertakings Compensation Committee of the Parties as set forth Board; provided that the Compensation Committee shall be under no obligation whatsoever to grant such discretionary Long-Term Incentive Grants. Any Long-Term Incentive Grants issued to Executive shall be governed by the Company's then-applicable long-term incentive plan(s) and any long-term incentive grant agreement(s) under the then applicable long-term incentive plan(s) under which they are issued.

(c) Benefits. During the Term, Executive shall be entitled to participate in all employee benefit plans, programs and arrangements (health, dental, disability, 401k, etc.) made available generally to the Company's senior executives or to its employees on substantially the same basis that

such benefits are provided to such senior executives; provided, however, that nothing in this Agreement and other good and valuable consideration, shall be construed to require the receipt and sufficiency of which is hereby acknowledged, and intending Company to establish or maintain any particular plans, programs or arrangements.

(d) Vacations. During the Term, Executive shall be entitled to 20 days paid time off ("*PTO*") days, to be legally bound, earned ratably throughout the Parties hereby agree as follows: year starting on the Commencement Date. PTO days may be only carried from one year to the next in accordance with the Company PTO policy,

provided that the Executive shall not be entitled to carry forward into the following year a balance of more than 10 PTO days.

1. (e) Reacquired Rights; Distribution Termination Reimbursement of Business Expenses. Executive is authorized to incur reasonable expenses in carrying out Executive's duties and Transition responsibilities under this Agreement and the Company shall reimburse Executive for all reasonable expenses, in accordance with and subject to the applicable policies and procedures of the Company. In addition, the Company shall promptly reimburse the Executive for all reasonable legal fees incurred by Executive in connection with the review, negotiation, drafting and execution of this Agreement, up to a cap of $5,000.

1.1. 5. This Termination of Employment.

(a) Termination by the Company for Cause or Termination by Executive without GoodReason, Death or Disability.

(i) In the event of a termination of Executive's employment by the Company for Cause, a termination by Executive without Good Reason, or in the event this Agreement will become effective November 9, 2022 (" terminates by reason of the death or Disability of Executive, Executive shall be entitled to any unpaid compensation accrued through the last day of Executive's employment, a lump sum payment in respect of all accrued but unused PTO days at Executive's Base Salary in effect on the date such PTO was earned, and payment of any other amounts owing to Executive but not yet paid, less any amounts owed by Executive to the Company (the "*Effective Date Accrued Amounts*").

1.2. Rockwell will reacquire the rights Executive shall not be entitled to distribute its Products directly to customers as set forth herein.

1.3. The Distribution Agreement will automatically terminate effective December 31, 2022, (the "**TerminationDate**"), subject to Section 5. The time period receive any other compensation or benefits from the Effective Date until Company whatsoever (except as provided below and as and to the Termination Date extent the continuation of certain benefits is the "**Transition Period**" required by law).

1.4. (ii) Rockwell is permitted during In the Transition Period case of a termination due to communicate with Baxter's and its affiliates' active, existing customers for the Products ("**Baxter Customers**") and set up Baxter Customers, including signing contracts and establishing invoicing and ordering processes, for Rockwell's Commercialization of Product with respect to the Baxter Customers after the Transition Period. Notwithstanding anything death or Disability, notwithstanding any provision to the contrary in any stock option, restricted stock or other equity award agreement between the Distribution Agreement Company and Executive, (x) all shares underlying Executive's time-based outstanding equity awards, including all options that are time-based awards (as opposed to performance-based) to acquire Company stock held by Executive (the "*Time-Based Awards*") shall accelerate and become fully vested upon the Date of Termination and shall thereupon remain fully exercisable until the earlier of (i) one (1) year from date of termination due to death or this Agreement, Rockwell Disability or (ii) the expiration of their stated terms.

(b) Termination by the Company without Cause or by Executive for Good Reason. If (x) Executive's employment is permitted during terminated by the Transition Period to communicate Company other than for Cause, death or Disability (i.e., without Cause) or (y) Executive terminates employment with Good Reason, then Executive will receive the Accrued Amounts and, Commercialize Products on the condition that the Executive signs a separation agreement containing a release of claims in the form attached as Exhibit C hereto (subject to any customers changes required by applicable law), which such release becomes final, binding and irrevocable within 30 days after the Date of Termination (or such longer period of time as required by applicable law), the Executive shall also be entitled to receive the following from the Company:

(i) An amount equal to the Executive's annualized Base Salary then in effect; payable in equal installments in accordance with the Company's regular payroll schedule, from the Date of Termination to the date that are not Baxter Customers; provided Rockwell shall obtain Baxter's prior written consent with respect to each non-Baxter Customer before doing so, such consent not to be unreasonably withheld, delayed or conditioned. Baxter will pass along any sales leads it receives to Rockwell during is 12 months after the Transition Period. During the Transition Period, Baxter shall not Commercialize Products to any customer other than the Baxter Customers, unless Baxter receives prior written consent from Rockwell to do so with respect to each non-Baxter Customer, such consent not to be unreasonably withheld, delayed or conditioned. Date of Termination (the "*Severance*

2. *Period*Product Customers"); provided, however, that each installment payable before the release becomes final, binding and irrevocable shall not be paid to the Executive until such release becomes final, binding and irrevocable (at which time all such amounts that would have been paid but for the delay described in this clause (i) shall be paid); provided further, however, that if the time period for the release to be executed and become irrevocable spans two calendar years, the installment payments due once the release becomes final, binding and irrevocable shall be paid no earlier than January 1 of the later calendar year;

2.1. (ii) Rockwell During the Severance Period, if Executive elects to continue Company medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 ("*COBRA*"), the Company shall until March 31, 2023, supply reimburse the Baxter Customers in **Attachment 1 (Extended Account)**Executive for the out-of-pocket cost of this Agreement with Products at the same prices and under continuing medical benefits, on the same terms offered and conditions as such benefits are provided to such Baxter Customers by Baxter immediately prior active employees of the Company, for up to 12 months. The Company's obligation under this Section 5(b)(ii) shall terminate or be reduced to the Effective Date, including, without limitation, terms relating to delivery, delivery costs, and order placement and fulfillment. Baxter represents and warrants extent that it has substantially similar coverage is provided Rockwell with complete and correct copies, selectively redacted by Baxter to certain remove non-relevant information, of all such terms prior a subsequent employer.

(iii) Subject to the Effective Date. Rockwell release becoming final, binding and irrevocable, notwithstanding any provision to the contrary in any stock option or restricted stock or other equity award agreement between the Company and the Executive, the Time-Based Awards shall have no obligation continue to supply vest over the Severance Period and all vested stock options to acquire Company stock and all other similar vested equity awards held by the Executive as of the Date of Termination shall continue to be exercisable for a period of one year from the Date of Termination, or, if earlier, until the ultimate expiration date of such Baxter Customers on such terms after March 31, 2023. awards; and

2.2. After the Termination Date, Rockwell shall assume responsibility for supplying Product to Baxter Customers listed in **Attachment 2 ("3PL Accounts")**. For avoidance of doubt, except as provided in Section 2.1, Rockwell shall have the right to supply and sell products to customers on terms and conditions specified by Rockwell in its sole discretion.

2.3. (iv) Notwithstanding anything the foregoing, if Executive engages in a material breach of any provision of this Agreement or the Distribution Confidentiality Agreement during the Severance Period (or the period applicable to such obligation, if shorter or longer), and such breach is not cured within ten business days after receipt from the Company of notice thereof, then the Company's continuing obligations under this Section 5(b) shall cease as of the date of the breach and the Executive shall be entitled to no further payments or benefits hereunder.

(c) Termination in connection with a Change of Control. In the event of a Change of Control, if Executive's employment is terminated by the Company other than for Cause or by Executive for Good Reason during the Effective Period, then Executive shall be entitled to receive the following from the Company:

(i) The Accrued Amounts;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Target Bonus, multiplied by the fraction obtained by dividing the number of days Executive was employed during the calendar year in which the Date of Termination occurs by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to 1.5 times the Executive's annual Base Salary then in effect (as determined without regard to any reduction in such Base Salary constituting Good Reason); *provided, however*, that if Executive's employment is terminated prior to the consummation of a Change of Control but under circumstances that would cause the Change of Control Date to precede the date

that the Change of Control is consummated, such amount will be paid in equal installments in accordance with the Company's regular payroll schedule over the Benefit Period (defined below), subject to all remaining installments being paid in a lump sum on the date on which the Change of Control is consummated;

(iv) If Executive elects to continue Company medical benefits under COBRA, for a period of 12 months following the Date of Termination (the "*Benefit Period*"), the Company shall reimburse the Executive for the out-of-pocket cost of continuing medical benefits for such

period on the same terms and conditions as such benefits are provided to active employees of the Company. The Company's obligation under this Section 5(c)(iv) shall terminate or be reduced to the extent that substantially similar coverage is provided by a subsequent employer.;

(v) Notwithstanding any provision to the contrary after in any stock option, restricted stock or other equity award agreement between the Company and Executive, all shares underlying Executive's Time-Based Awards shall accelerate and become fully vested upon the Date of Termination Date, Baxter: (a) is permitted to sell any Product Baxter purchased prior to the Termination Date but still in Baxter's inventory (e.g., in transit or with a 3PL) ("**Remaining Inventory**") until such inventory is fully depleted solely to Baxter Customers that are individual persons who utilize Products at their place of residence for dialysis therapy at home; or (b) may also elect to sell to Rockwell up to **[***]** (inclusive of freight and warehousing costs) worth of the Remaining Inventory, and Rockwell hereby agrees to buy up to **[***]** (inclusive of freight and warehousing costs) worth of such Remaining Inventory, at a price equal to the price paid by Baxter to Rockwell for such Product and Rockwell also agrees to pay freight and warehousing costs incurred by Baxter with respect to such Product (such costs not to exceed 10% of the total value of the Remaining Inventory). **[***]**.

2.4. Rockwell shall not discriminate against any Baxter Customer during the Transition Period, including, but not limited to, with respect to: the allocation of supply, application of fees and pass-through of costs, fulfillment and delivery of orders, Customer Service, Transportation Services, and technical support, and shall use commercially reasonable efforts to continue to continue to supply Products to Baxter Customers consistent with past practice through the end of the Transition Period. During the Transition Period, Baxter shall not discriminate against Rockwell with respect to Baxter Customers, including without limitation in bundling of products or promoting other suppliers of the Products, and shall use commercially reasonable efforts to continue to sell Products consistent with past practice through the end of the Transition Period.

2.5. Until February 15, 2023, Rockwell may request, and Baxter shall provide, reasonable support of Rockwell's onboarding of Baxter Customers, and Baxter may request, and Rockwell shall provide, reasonable support of Baxter's transition and wind-down of its Product sales relationships with Baxter Customers. Rockwell will be responsible for operating its own sales, service, logistics, and other business operations, including, without limitation, sales, marketing, contracting, customer service, invoicing and collections, and delivery; Baxter may provide information and other reasonable support requested by Rockwell to assist Rockwell until February 15, 2023, but Baxter is not obliged to perform any business operations for or on behalf of Rockwell.

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2.6. Baxter makes no representation, warranty, or guarantee that any Baxter Customer will transition to a supply relationship directly with Rockwell or that Rockwell will realize any value or volume of Product sales after the Effective Date. Baxter makes no representation, warranty, or guarantee regarding the value of Baxter Customer relationships. Rockwell acknowledges Baxter does not control or direct Baxter Customer's purchasing decisions, and Customers have sole discretion to decide to source concentrates from Rockwell or from any other concentrates supplier.

3. **Financial Matters.** Each Party acknowledges and agrees that the following terms shall replace all financial and pricing terms, payments and amounts owed from either Party to the other Party under the Distribution Agreement and that no additional payments of any kind is due from Baxter to Rockwell or from Rockwell to Baxter with respect to the Distribution Agreement, including, without limitation, Contract Price Adjustments, True-Up Payments, Delivery Fees, Freight Fees, Economic Value Transfer Payments, Transportation Cap Credit or Correction Payments, whether accrued before or after the Termination Date, except as follows:

3.1. **Product Price**. Rockwell agrees to sell Products to Baxter ordered by Baxter after the Effective Date until the Termination Date at the prices set forth in the "Rockwell Standard Price" column in **Attachment 3**. Such prices are fixed and will be deemed the Contract Price under the Distribution Agreement. Baxter shall pay unpaid invoices for Product purchases made before the Effective Date, and for Product purchases made before the Termination Date, in accordance with Section 4.4 of the Distribution Agreement. During the Transition Period, each Party shall continue consistent with past practice to pass-through to the other any payments such Party collects from a Baxter Customer pursuant to invoices issued by the other Party. During and after the Transition Period, if a customer payment is received by one Party that should have been made to the other Party for an invoice issued by such Party, then the receiving Party shall promptly notify the other Party of such

customer payment and both Parties shall reasonably cooperate with one another and assist customers to ensure such mis-directed customer payments are received by the invoicing Party.

3.2. **True-Up Notice Payment.** Upon execution of this Agreement, Baxter shall pay **[***]** as full and final satisfaction of the amount owed pursuant to Section 4.3(d) and (f) of the Distribution Agreement for Contract Price adjustments for the 2021 calendar year and as full satisfaction of the True-Up Notice for 2021. Baxter will owe no additional amounts as True-Up payments for Contract Price adjustments.

3.3. **Customer Service and Transportation Services Payments.**

3.3.1. As full and final payment for Customer Services provided and to be provided by Rockwell in calendar year 2022, upon execution of this Agreement Baxter shall pay Rockwell **[***]**; Baxter will not owe any additional amount for Customer Services under the Distribution Agreement, other than the 1.5% of Customer Service Cost management fee.

3.3.2. Baxter shall pay Rockwell the amount set forth in the "Rockwell Distribution Costs" column in **Attachment 3** for Transportation Services provided from October 1, 2022 through the end of the Transition Period, including any additional rush order delivery charges and/or late fees; Baxter will not owe any additional amount for Transportation Services, and shall not owe any Transportation Services related management fee, for this time period. For services provided prior to October 1, 2022, Baxter's payment for Transportation Services restrictions thereon shall be made lifted in accordance with the terms of the Distribution stock option or other award agreements evidencing such Time-Based Awards, and all such exercisable time-based stock options shall continue to be exercisable for the remainder of their stated terms; and

(vi) Notwithstanding the foregoing, if Executive engages in a material breach of any provision of this Agreement or Executive's Confidentiality Agreement during the Benefits Period, and such breach is not cured within ten business days after receipt from the Company of notice thereof, then in effect. the Company's continuing obligations under this Section 5(c) shall cease as of the date of the breach and the Executive shall be entitled to no further payments or benefits hereunder.

6. Notice of Termination.

(a) Any termination of Executive's employment by the Company for Cause, or by Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 10. For purposes of this Agreement, "*Notice of Termination*" means a written notice which: (i) is given at least 10 days prior to the Date of Termination (at least 30 days in the case of Notice of Termination given by Executive for Good Reason, following the notice and cure period set forth below in the definition of Good Reason);
[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. (ii) indicates the specific termination provision in this Agreement relied upon; (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated; and (iv) specifies the employment termination date.

(b) A termination of employment of Executive will not be deemed to be for Good Reason unless Executive gives the Notice of Termination provided for herein within 30 days after Executive has actual knowledge of the act or omission of the Company constituting such Good Reason and Executive gives the Company a 30-day cure period to rectify or correct the condition or event that constitutes Good Reason and Executive delivers final Notice of Termination within 30 days of the date that Company's failure to cure deadline has expired, which final Notice of

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Termination must specify a Date of Termination of no later than 30 days after the final Notice of Termination is provided.

3.3.3. 7. Rockwell Mitigation of Damages. Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 5(b)(ii) and 5(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by Executive as the result of self-employment or employment by another employer or otherwise.

8. Excess Parachute Excise Tax.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall invoice Baxter be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the services described in Sections 3.3.1 and 3.3.2 benefit of Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 8) (a "*Payment*") would be subject to the Distribution Agreement, provided Rockwell Distribution Costs excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "*Excise Tax*"), the Company will automatically reduce such Payments to the extent, but only to the extent, necessary so that no portion of the remaining Payments will be invoiced separately at subject to the end Excise Tax, unless the amount of each month for such Payments

that the prior month and shall be payable within 45 days Executive would retain after receipt. The invoice will include such detail and be provided in such format as reasonably requested by Baxter, and will at a minimum include information by customer name, order date, delivery date, each unit ordered, each unit delivered and the corresponding distribution costs of each unit.

3.4. **Non-Inventory Related Payments.** As full and final payment of the amounts owed Excise Tax and all applicable Federal, state and local income taxes without such reduction would exceed the amount of such Payments that the Executive would retain after payment of all applicable Federal, state and local taxes after applying such reduction. Unless otherwise elected by Baxter for the items listed Executive to the extent permitted under Code Section 409A, the Company shall reduce or eliminate the Payments by first reducing or eliminating any cash severance benefits (with the payments to be made furthest in the chart future being reduced first), then by reducing or eliminating any accelerated vesting of stock options or similar awards, then by reducing or eliminating any accelerated vesting of restricted stock or similar awards, then by reducing or eliminating any other remaining Payments; provided, that no such reduction or elimination shall apply to any non-qualified deferred compensation amounts (within the meaning of Section 409A of the Code) to the extent such reduction or elimination would accelerate or defer the timing of such payment in **Attachment 4,** upon execution manner that does not comply with Section 409A of this Agreement Baxter shall pay **[***]**. the Code.

3.5. (b) Invoicing. Except as otherwise or additionally provided All determinations required to be made under this Section 8, including the assumptions to be utilized in Section 3.3 above, Rockwell arriving at such determination, shall invoice Baxter in accordance with Section 4.4 of the Distribution Agreement.

3.6. **Rockwell Reacquisition Rights Payment to Baxter.** As consideration for this Agreement and Rockwell's reacquisition of Product Commercialization rights granted exclusively to Baxter under the Distribution Agreement earlier than such rights would have terminated pursuant to the terms of the Distribution Agreement, Rockwell shall pay Baxter **[***]**.

3.7. **Right to Offset.** Baxter is permitted to, and Rockwell hereby expressly grants Baxter the right to, offset payments due from Baxter to Rockwell, including, without limitation, those amounts due under Section 3.3, against any unpaid amounts due from Rockwell to Baxter pursuant to Section 3.6 that are not paid by Rockwell be made by the applicable due date set forth in Section 3.6.

3.8. Company's independent auditors or such other certified public accounting firm reasonably acceptable to Executive as may be designated by the Company (the "*Default.* Rockwell's failure to pay to Baxter any Installment on or before the date that the Installment becomes due and payable under Section 3.6 constitutes an event of default of this Agreement ("**Default**").

3.8.1. **Notice of Default.** Baxter shall provide written notice by email and regular mail to Rockwell that a Default has occurred ("**DefaultNotice Accounting Firm**") as provided in Section 11.9 which shall provide detailed supporting calculations both to the Company and Executive within 15 business days of the Distribution Agreement.

3.8.2. **Opportunity to Cure.** Upon receipt of notice from Executive that there has been a Default Notice, Rockwell shall have five (5) calendar days to cure Payment, or such earlier time as is requested by the Default ("**CurePeriod**"). If Rockwell cures the Default within the Cure Period, it will no longer be in Default.

3.8.3. **No Waiver of Default.** Baxter's acceptance of any Installment hereunder which is not timely or is less than the full amount due Company. All fees and payable at the time of such Installment shall not constitute a waiver of Baxter's right to pursue any available remedies at that time or at any subsequent time or nullify actions already undertaken by Baxter to enforce any such remedy, or in any way or manner prejudice, impair, diminish, or restrict any right, power, or remedy available to Baxter under this Agreement. Any delay by Baxter in sending a Default Notice shall not constitute a waiver of its rights to enforce this Agreement or a Default hereunder.

3.8.4. **Remedy.** If Rockwell fails to cure the Default within the Cure Period, any remaining balance expenses of the **[***]** Installments due under this Agreement that has not yet been paid to Baxter Accounting Firm shall be borne solely by Rockwell will become immediately due the Company. Any determination by the Accounting Firm shall be binding upon the Company and payable to Baxter. **[***]. Executive.**

4. **Customer Communications, Public Statements, and Non-Disparagement.** Neither Party shall make any statement to the marketplace, customers, or any public statements about the Parties' relationship and the supply of Products without coordinating with the other Party.

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Baxter will have the right to direct the communication strategy 9. Legal Fees. Each party shall be responsible for its own legal fees and expenses in connection with Baxter Customers and any other Baxter Customer communication reasonably related to the relationship between Baxter and Rockwell, including the right to draft any written communication on behalf of Baxter claim or both Baxter and Rockwell, provided that Rockwell will have the right to reasonably consent to such communications mentioning Rockwell. Neither Rockwell nor Baxter shall engage in any conduct or make any statement disparaging or criticizing the other Party or its Affiliates, or any products or services offered by the other Party or its Affiliates. Both Parties shall protect the terms of this Agreement, including, without limitation, the provisions set forth in Section 3 (Consideration and Financial Matters) as Confidential Information under the Distribution Agreement. Notwithstanding the forgoing or anything else to the contrary, Rockwell may make such disclosures and communications that are necessary to comply with applicable securities laws, the rules and regulations of the Securities and Exchange Commission, U.S. generally accepted accounting principles, or with an Order issued by a court or regulatory body with competent jurisdiction.Rockwell shall provide Baxter with prior written notice of its intent to make such disclosure or communication at least five (5) calendar days in advance of such disclosure or communication if reasonably practicable.

5. Contract Operations.

5.1. The Parties mutually acknowledge and agree that this Agreement amends the Distribution Agreement as provided herein, and the terms of this Agreement will control and supersede over any conflicting terms in the Distribution Agreement.

5.2. Except for terms expressly defined herein, references to any of defined terms herein will have the same meaning and effect in this Agreement as they had in the Distribution Agreement.

5.3. The following provisions of the Distribution Agreement are hereby deleted from the Distribution Agreement and will be of no force or effect after the Effective Date: Section 1.3 (Original Customer Contracts); Section 1.4 (Promotional and Training Material); Section 1.5 (Transition Services); Section 3.1 (Forecasts); the first, fourth and fifth sentences of Section 3.3 (Manufacturing Capacity) only (but excluding clauses (d) and (f) of such fifth sentence); Section 3.4 (Option to Assume Manufacturing); Section 3.8 (Minimum Requirements); Section 3.9 (West Coast Facility); Section 3.10 (Joint Steering Committee); Section 3.11 (Key Person); Section 4.1 (Upfront Payment); Section 4.2 (Contract Price – 2014); Section 4.3 (Contract Price – Balance of the Term); Section 4.5 (West Coast Facility Fee); Section 4.6 (Refund of Upfront Payment and West Coast Facility Fee); Section 10.1 (Term); Section 10.2(c) (Contract Price Increase); Section 10.2(d) (Change of Control); Section 10.2(e) (Distributor's Option); Section 10.4 (Fulfillment of Customer Contracts); Section 10.5 (Remaining Inventory); Section 11.17 (Debt Payment; Restriction on Liens); Exhibit E (Gallon Conversion Formulas); Exhibit F (Estimated COGS Methodology); and Exhibit J (Price Schedule).

5.4. The following provisions of the Distribution Agreement are hereby amended as set forth below:

1.1.1. The Distributor Rights are amended to be non-exclusive and any other references to exclusive rights or grants or other exclusivity are amended to be non-exclusive.

1.1.2. Exhibit C (Support Services) is deleted in its entirety and is replaced by **Attachment 5 (New Exhibit C)**dispute relating to this Agreement.

1.1.3. 10. Section 10.3 (Surviving Rights Notices. All notices, requests, demands and Obligations) is amended to remove Article 10 (Term other communications hereunder shall be in writing and Termination) from the list of surviving rights and obligations, and to add Section 10.3 (Surviving Rights and Obligations) and Section 10.6 (Noncompetition) as surviving provisions.

1.1.4. Section 10.6 (Noncompetition) is amended to replace it with the following: "For a period of two years from the Termination Date, the Distributor and its Affiliates shall not manufacture or Commercialize any Rockwell Competitive Products in the United States, other than the Excluded Products." In addition, for purposes of this amended Section 10.6, "Effective Date" in the definition of Excluded Products will be deemed to also mean have been duly given if delivered by hand, upon confirmation of a facsimile or email transmission or upon receipt

when mailed within the Termination Date defined in Section 1.2 of this Agreement. continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

1.1.5. Section 11.9 (Notices) is amended to replace the notice information with the following updated addresses:

If if to the Company:

Rockwell Medical, Inc.
30142 S. Wixom Road
Rd.
Wixom, MI 48393
Attention: Mark Strobeck,
Attn: President and Chief Executive Officer
Email: mstrobeck@rockwellmed.com if to Executive:

The address on file with a copy (which will not constitute notice) to: the records of the Company

Rockwell Medical, Inc.
30142 Wixom Road
Wixom, MI 48393
Attention: Megan Timmins, Senior Vice President & General Counsel
Email: mtimmins@rockwellmed.com

If Addresses may be changed by written notice sent to the Distributor:

Baxter Healthcare Corporation

One Baxter Parkway
Deerfield, Illinois 60015
Attention: General Counsel
Telecopy: 224.948.2000 other party at the last recorded address of that party.

5.5. 11. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

12. Entire Agreement. This Agreement, together with Exhibit A and the Confidentiality Agreement, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all other prior agreements, written or oral, with respect thereto.

13. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this Agreement or any dispute or claim between Executive and the Company or its officers, directors, agents, or employees (a "*Dispute*"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked 'Arbitration Demand.' Such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 13. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The following Dispute shall be resolved by a single arbitrator in an arbitration administered by the American Arbitration Association in accordance with its Employment Arbitration Rules and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The decision of the arbitrator shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrator may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 13 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the Distribution Agreement are hereby expressly incorporated into this Agreement office of the American Arbitration Association ("*AAA*") located in New York, New York or such other AAA office as if fully set forth herein: Section 8.1 (Mutual Representations), Article 9 (Confidentiality), Article 11 (Miscellaneous) (except 11.17 (Debt Payment; Restriction on Liens)) the parties may agree upon (without any obligation to so agree). Any reference in these provisions as incorporated herein The arbitration shall be conducted pursuant to the Agreement will Employment Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be deemed to completed in a 60-day period. In addition, the following rules and procedures shall apply to this Agreement. the arbitration:

6. (i) Fees The arbitrator shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and Expenses. whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 13.

(ii) The decision of the arbitrator, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each Party hereto party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrator hereunder.

(iii) The arbitrator shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory and punitive damages if authorized by applicable law.

(iv) The parties shall bear its their own fees costs in preparing for and expenses (including attorneys' fees) incurred participating in the resolution of any Dispute pursuant to this Section 13, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 13(a), the provisions of this Section 13 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 13 shall pay the Distribution costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

14. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of Delaware without regard to the application of choice- of-law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the consummation balance of the transactions contemplated hereby.

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7. **Representations.** Each Party hereby represents Agreement shall be interpreted as if such provision were so excluded and warrants that it has not assigned or otherwise conveyed or delegated, shall be enforceable in whole or in part, any claim or right that it has or may have under the Distribution Agreement to any third party or person. Each Party represents that the execution and delivery of this Agreement is the duly authorized and binding act of the Party, and that the Party's signatory hereto is duly authorized to execute this Agreement on behalf of the Party. accordance with its terms.

8. **No Admission of Liability.** Baxter and Rockwell expressly agree and acknowledge that their entering into this Agreement shall not be construed in any manner as an admission of any liability, obligation, or wrongdoing on the part of either Party. Each Party expressly denies any and all liability or wrongdoing with respect to the Distribution Agreement.

9. **Limitation of Representations and Warranties.** ROCKWELL REPRESENTS AND ACKNOWLEDGES THAT ANY RIGHTS AND ASSETS ACQUIRED BY ROCKWELL PURSUANT TO THIS AGREEMENT (COLLECTIVELY, THE "**ACQUIRED ASSETS**") ARE BEING SOLD TO ROCKWELL ON AN "AS IS, WHERE IS" BASIS, WITHOUT ANY WARRANTIES OR REPRESENTATIONS, EITHER EXPRESS OR IMPLIED, OF ANY NATURE WHATSOEVER INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR CAUSE.

10. **Cooperation between the Parties.** Each Party shall fully cooperate with the other Party with respect to the performance of this Agreement. Each Party will provide or make available to the other Party any information and will execute, acknowledge and deliver such further documents that may

reasonably be required in order to effectively perform this Agreement and to evidence the termination of the Distribution Agreement, and to release all obligations and liabilities of the Parties thereunder.

11. (d) Binding Agreement. Effect. This Agreement shall be binding upon and inure to the benefit of the successors, assigns beneficiaries, heirs and legal representatives of Executive (including the Parties. There are Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no third-party beneficiaries to such succession had taken place. Regardless of whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement. Each Party acknowledges

(e) Successors and agrees that it fully understands Assigns. Except as provided in Section 14(d) in the provisions set forth case of the Company, or to the Beneficiary in the case of the death of Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their effect, and that each Party is voluntarily entering into this Agreement. nature extend beyond the termination of the Term shall survive such termination.

12. (h) Counterparts; Electronic or Facsimile Transmission. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document. Signatures to this Agreement may be delivered by any electronic means.

15. Section 409A of the Code. The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be construed and interpreted in accordance with such intent. Executive's termination of employment (or words to similar effect) shall not be deemed to have occurred for purposes of this Agreement unless such termination of employment constitutes a "separation from service" within the meaning of Code Section 409A and the regulations and other guidance promulgated thereunder.

(a) Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed on the date of Executive's termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B) and using the identification methodology selected by the Company from time to time, or if none, the default methodology set forth in Code Section 409A, then with regard to any payment or the providing of any benefit that constitutes "non-qualified deferred compensation" pursuant to Code Section 409A and the regulations issued thereunder and not exempt from Code Section 409A as a short-term deferral or otherwise that is payable due to Executive's separation from service, to the extent required to be delayed in compliance with Code Section 409A(a)(2)(B), such payment or benefit shall not be made or provided to Executive prior to the earlier of (i) the expiration of the six (6) month period measured from the date of Executive's separation from service, and (ii) the date of Executive's death. On the first day of the seventh month following the date of Executive's separation from service or, if earlier, on the date of Executive's death, all payments delayed pursuant to this Section 15(a) shall be paid or reimbursed to Executive in a lump sum, and any remaining payments and benefits due to Executive under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(b) To the extent any reimbursement of costs and expenses provided for under this Agreement constitutes taxable income to Executive for Federal income tax purposes, such reimbursements shall be made no later than December 31 of the calendar year next following the calendar year in which the expenses to be reimbursed are incurred. With regard to any provision herein that provides for reimbursement of expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year. Any tax gross-ups provided for under this Agreement shall in no event be paid to Executive later than the December 31 of the calendar year following the calendar year in which the taxes subject to gross-up are incurred or paid by Executive.

(c) If any amount under this Agreement is to be paid in two or more installments, for purposes of Code Section 409A each installment shall be treated as a separate payment.

16. Indemnification. During Executive's employment, the Company shall maintain directors' and officers' liability insurance that is applicable to Executive. The Company shall indemnify Executive and hold Executive harmless from and against any claim, loss or cause of action arising from or out of Executive's performance prior to or after the Commencement Date (and within the scope of her employment) as an officer, director or employee of the Company or any of its subsidiaries or other affiliates or predecessors or in any other capacity, including any fiduciary capacity, in which Executive serves at the Company's request, in each case to the maximum extent permitted by applicable corporate law and, to the extent more favorable, to the maximum extent permitted under the Company's Certificate of Incorporation and By-Laws. On the Commencement Date, the Company shall execute and deliver to Executive an Indemnification Agreement, in the form adopted by the Board, pursuant to which the Company agrees to indemnify Executive and advance defense costs and expenses. The rights under this Section 16 shall in all cases be on terms no less favorable to Executive than to other senior executives of the Company

and shall survive the termination of employment until the expiration of the applicable statute of limitations.

17. Executive Acknowledgement. Executive hereby acknowledges that Executive has read and understands the provisions of this Agreement, that Executive has been given the opportunity for Executive's legal counsel to review this Agreement, that the provisions of this Agreement are reasonable, and that Executive has received a copy of this Agreement.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Employment Agreement to be executed as of the Effective Date.

ROCKWELL MEDICAL, INC.

By: /s/ Russell H. Ellison, MD Name: Russell H. Ellison, MD
Title: President & CEO

EXECUTIVE

/s/ Megan C. Timmins
Megan C. Timmins Date July 29, 2021

EXHIBIT A

(a) "*Beneficiary*" means any individual, trust or other entity named by Executive to receive the payments and benefits payable hereunder in the event of the death of
Executive. Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel or Secretary of the Company. Executive may change her designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by Executive, or if no designated Beneficiary survives Executive, then the payment and benefits provided under this Agreement, if any, will be paid to Executive's estate, which shall be deemed to be Executive's Beneficiary.

(b) "*Cause*" means: (i) Executive's material breach of this Agreement or any other material policy of the Company, in each instance only after a written demand to cure such breach is delivered to Executive setting forth in reasonable detail the circumstances of such breach and Executive fails to cure such breach (if it reasonably can be cured) within the thirty (30) day period following her receipt of such written notice; (ii) Executive's continued willful neglect of Executive's duties with the Company or willful failure to comply with an original express lawful written directive relating to Executive's duties (other than as a result of Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to Executive, which specifically identifies the manner in which the Company believes that Executive has neglected her duties or failed to comply with a lawful directive and Executive fails to comply with such written demand within the thirty (30) day period following its receipt; (iii) any material act of dishonesty, or any act of misappropriation, embezzlement, fraud or similar conduct involving the Company or any of its affiliates; (iv) the conviction of or the plea of nolo contendere or the equivalent by Executive of a felony or other crime involving moral turpitude; or (v) Executive's engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company. No act or failure to act by Executive shall be
considered "willful" unless it is done or omitted to be done by Executive in bad faith and without reasonable belief that she was acting in the best interests of the Company.

(c) "*Change of Control*" means a "Change in Control" as defined in the Plan.

(d) "*Change of Control Date*" means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if
Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by Executive that such termination or event: (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) "*Code*" means the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

(f) "*Date of Termination*" means the date specified in a Notice of Termination pursuant to Section 6 hereof, or Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) "*Disability*" means a mental or physical condition that renders Executive substantially incapable of performing her duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) "*Effective Period*" means the period beginning on the Change of Control Date and ending 18 months after the date of the related Change of Control.

(i) "*Good Reason*" means, subject to the notice and cure provisions set forth in Section 6(b), and unless Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to Executive of any duties materially inconsistent with Executive's position under this Agreement, including any material change in status, title, authority, reporting, duties or responsibilities, or other action which results in a material diminution in Executive's authorities, duties, responsibilities or reporting; (ii) a reduction in Executive's Base Salary by the Company of more than 5%, unless such reduction is made proportionately in connection with
broader salary reductions among all of the Company's executive officers; (iii) the relocation of Executive's principal work location of more than 30 miles; or (iv) the Company's material breach of this Agreement or any other material written agreement between the Company and Executive.

EXHIBIT B

EMPLOYEE CONFIDENTIALITY, ASSIGNMENT OF INVENTIONS, NON- INTERFERENCE AND NON-COMPETITION AGREEMENT

The following is an agreement ("*Agreement*") is made as of July 16, 2021 between Megan C. Timmins and Rockwell Medical, Inc., a Delaware corporation (the "*Company*"), and any successor in interest, and me, Megan C. Timmins, and this Agreement is a material part of the consideration for my Employment Agreement with the Company:

1. Job Title and Responsibility. I understand that my job title with the Company will be SVP, General Counsel and Secretary. My job duties and responsibilities will be those set forth in my Employment Agreement with the Company.

2. Consideration. I understand that the consideration to me for entering into this Agreement is my Employment Agreement with the Company, and I agree that this consideration is fully adequate to support this Agreement.

3. Proprietary Information. I acknowledge that the Company is engaged in a continuous program of research, development and production. I also acknowledge that the Company possesses or has rights to secret, private, confidential information and processes (including processes and information developed by me during my employment by the Company) which together are valuable, special and unique assets of the Company and which have commercial value in the Company's business ("*Proprietary Information*"). Proprietary Information includes, but is not limited to, information and details regarding the Company's business, trade or business secrets, inventions, intellectual property, systems, policies, records, reports, manuals, documentation, models, data and data bases, products, processes, operating systems, manufacturing techniques, research and development techniques and processes, devices, methods, formulas, compositions, compounds, projects, developments, plans, research, financial data, personnel data, internal business information, strategic and staffing plans and practices, business, marketing, promotional or sales plans, practices or programs, training practices and programs, costs, rates and pricing structures and business methods, computer programs and software, customer and supplier identities, information and lists, confidential information regarding customers and suppliers, and contacts at or knowledge of Company suppliers and customers or of prospective or potential customers and suppliers of the Company. Excluded from the definition of Proprietary Information is information that is or becomes part of the public domain, other than through the breach of this Agreement by Executive. For this purpose, information known or available generally within the trade or industry of the Company or any affiliate shall be deemed to be one known or available to the public and not to be Proprietary Information.

4. Obligation of Confidentiality. I understand and agree that my employment creates a relationship of confidence and trust between the Company and me with respect to (i) all Proprietary Information, and (ii) the confidential information of others with which the Company has a business relationship. At all times, both during my employment by the Company and after the termination of my employment (whether voluntary or involuntary), I will keep in confidence and trust all such information, and I will not use, reveal, communicate, or disclose any such

Proprietary Information or confidential information to anyone or any entity, without the written consent of the Company, unless I am ordered to make disclosure by a court of competent jurisdiction. Notwithstanding any other provision in this Agreement or any other agreement, if I make a confidential disclosure of a Company trade secret to a government agency, government official or an attorney for the purpose of reporting or investigating a suspected violation of law, or in a court filing under seal, I will not be held liable under this Agreement or any other agreement, or under any federal or state trade secret law for such a disclosure. Moreover, nothing in this Agreement or any other agreement shall prevent me from making a confidential disclosure of any other Proprietary Information to a government official, to an attorney as necessary to obtain legal advice or in a court filing under seal or otherwise as required by law.
By signing this Agreement, I agree to waive my right to recover individual relief based on any claims asserted in such a complaint or charge; provided, however, that nothing in this Agreement limits my right to receive an award for information I provide to any government agencies that are authorized to provide monetary or other awards to eligible individuals who come forward with information that leads to an agency enforcement action.

5. Ownership, Disclosure and Assignment of Proprietary Information andInventions. In addition, I hereby agree as follows:

(a) Ownership and Assignment. All Proprietary Information is, and shall be, the sole and exclusive property of the Company and its successors and assigns, and the same instrument. Company and its successors and assigns shall be the sole and exclusive owner of all Proprietary Information, including, but not limited to, trade secrets, inventions, patents, trademarks, copyrights, and all other rights in connection with such Proprietary Information. I agree that I have no rights in Proprietary Information. I hereby assign, and shall assign, to the Company and its successors and assigns any and all rights, title and interest I may have or acquire in Proprietary Information. Any copyrightable work prepared in whole or in part by me in the course of my employment shall be deemed “a work made for hire” under applicable copyright laws, and the Company and its successors and assigns shall own all of the rights in any copyright.

(b) Return of Materials and Property. All documents, records, apparatus, equipment, databases, data and information, whether stored in physical form or by electronic means, and all electronic, computer, intellectual, and physical property (“*Materials and Property*”), whether or not pertaining to Proprietary Information, furnished to me by the Company or produced by me or others in connection with employment, shall be and remain the sole and exclusive property of the Company. I shall return to the Company all Materials and Property as and when requested by the Company. Even if the Company does not so request, I shall return all Materials and Property upon termination of employment by me or by the Company for any reason, and I will not take with me any Materials and Property, or any reproduction thereof, upon such termination.

(c) Notification. During the term of my employment and for one (1) year thereafter, I will promptly disclose to the Company, or any persons designated by it, all improvements, inventions, intellectual property, works of authorship, formulas, ideas, processes, techniques, discoveries, developments, designs, devices, innovations, know-how and data, and creative works in which copyright and/or unregistered design rights will subsist in various media
(collectively, “*Inventions*”), whether or not such Inventions are patentable, which I make or

conceive, contribute to, reduce to practice, or learn, either alone or jointly with others, during the term of my employment.

(d) Ownership of Inventions. I agree and acknowledge that all Inventions which I make, conceive, develop, or reduce to practice (in whole or in part, either alone or jointly with others) at any time during my employment by the Company, and (i) which were created using the equipment, supplies, facilities or trade secret information of the Company; or (ii) which were developed during the hours for which I was compensated by the Company; or (iii) which relate, at the time of conception, creation, development or reduction to practice, to the business of the Company or to its actual or demonstrably anticipated research and development; or (iv) which result from any work performed by me for the Company, shall be the sole and exclusive property of the Company and its successors and assigns (and to the fullest extent permitted by law shall be deemed works made for hire), and the Company and its successors and assigns shall be the sole and exclusive owner of all Inventions, patents, copyrights and all other rights in connection therewith. I hereby assign to the Company any and all rights I may have or acquire in such Inventions. I agree that any such Invention required to be disclosed under paragraph (c), above, within one (1) year after the termination of my employment shall be presumed to have been conceived or made during my employment with the Company and will be assigned to the Company unless and until I prove and establish to the contrary.

(e) Assistance and Cooperation. With respect to Inventions described in paragraph (d), above, I will assist the Company in every proper way (but at the Company’s expense) to obtain, and from time to time enforce, patents, copyrights or other rights on these Inventions in any and all countries and will execute all documents reasonably necessary or appropriate for this purpose. This Agreement may be delivered by one obligation

shall survive the termination of my employment. In the event that the Company is unable for any reason whatsoever to secure my signature to any document reasonably necessary or both Parties by facsimile appropriate for any of the foregoing purposes (including renewals, extensions, continuations, divisions or electronic transmission continuations in part), I hereby irrevocably designate and appoint the Company, and its duly authorized officers and agents, as my agents and attorneys-in- fact to act for and in my behalf and instead of me, but only for the purpose of executing and filing any such document and doing all other lawfully permitted acts to accomplish the foregoing purposes with the same legal force and effect as if delivered personally. executed by me.

13. (f) Entire Agreement; Modification. Exempt Inventions This . I understand that this Agreement is does not require assignment of an Invention for which no equipment, supplies, facilities, resources, or trade secret information of the entire Agreement between Company was used, and which was developed entirely by me on my own time, unless the Parties with respect invention relates (i) directly to the business of the Company or (ii) to the Company's actual or demonstrably anticipated research or development. However, I will disclose to the Company any Inventions I claim are exempt, as required by paragraph (c) above, in order to permit the Company to determine such issues as may arise. Such disclosure shall be received in confidence by the Company.

6. Prior Inventions. As a matter of record, I attach hereto as Exhibit I a complete list of all inventions or improvements relevant to the subject matter hereof of my employment by the Company which have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment with the Company, that I desire to remove from the operation of this Agreement, and supersedes any prior Agreement or communications between the Parties, whether written, oral, electronic or otherwise, unless otherwise expressly provided for in this Agreement. No change, modification, amendment, or addition of or I covenant that such list is complete. If no such list is attached

to this Agreement, I represent that I have no such inventions and improvements at the time of my signing this Agreement.

7. Other Business Activities. So that the Company may be aware of the extent of any other demands upon my time and attention, I will disclose to the Company (such disclosure to be held in confidence by the Company) the nature and scope of any other business activity in which I am or become engaged during the term of my employment. During the term of my employment, I will not engage in any business activity or employment which is in competition with, or is related to, the Company's business or its actual or demonstrably anticipated research and development, or that will affect in any manner my ability to perform fully all of my duties and responsibilities for the Company.

8. Non-Interference and Non-Solicitation of Employees, Customers and Others.

(a) During my employment with the Company and for twelve (12) months after the termination of my employment (whether the termination is by me or the Company, the "*Restricted Period*"), I will not, and will not attempt to directly or indirectly do any one or more of the following: (i) induce, encourage or solicit any employee, consultant, or independent contractor of the Company to leave the Company for any reason, unless specifically requested to take such action in writing by the Company; or (ii) employ, retain, or engage any employee, consultant, or independent contractor of the Company. For purposes of this Section 8(a), the terms "employee", "consultant" and "independent contractor" shall include those who served in such capacities within six (6) months preceding the date of the termination of my employment; provided, that nothing herein shall prevent me from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor if such discussions shall be valid unless in writing and signed by authorized representatives held as a result of, or any employment shall be the result of, the Parties. Each Party hereto has received response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent legal advice regarding contractor.

(b) During the Restricted Period, I will not, and will not attempt to, directly or indirectly, solicit, divert, disrupt, interfere with or take away any Company customer, supplier, agent, vendor, distributor, representative, or other contracting party with the Company that had such a relationship with the Company during my employment with the Company to a business that is a Competitor of the Company. For purposes of this Agreement, the term "*Competitor*" shall include any company or other entity engaged in developing or commercializing any one or more of the following: (i) drug products, drug therapies and their respective rights concentrates/dialysates that target end-stage renal disease and chronic kidney disease for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis or (ii) any product or process developed and commercialized, or under development in whole or in part, by the Company during my employment.

(c) During the Restricted Period, I will not, and will not attempt to, directly or indirectly induce any customer, supplier, agent, vendor, distributor, representative, or other contracting party with the Company that had such a relationship with the Company during my employment with the Company, to reduce its patronage of the Company or to terminate any written or oral agreement or understanding, or any other business relationship with the Company.

9. Non-Competition During and After Employment. During the Restricted Period, I will not directly or indirectly, without the prior written consent of the Company, maintain a relationship with a Competitor including as an employee, employer, consultant, agent, lender, investor, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity; provided that, nothing in this

Agreement shall prohibit me from being a passive owner of not more than three percent (3%) of the outstanding equity of any entity that itself or through its affiliates in engaged in various businesses including a business that would be considered a Competitor as long as I have no involvement with the competitive business. I understand and agree that the restrictions in this paragraph are necessary and reasonable to protect the legitimate business interests of the Company.

10. Obligations to Former Employers. I represent that my execution of this Agreement, my employment with the Company, and my performance of my duties and proposed duties to the Company will not violate any obligations or agreements I have, or may have, with any former employer or any other third party, including any obligations and agreements requiring me not to compete or to keep confidential any proprietary or confidential
information. I have not entered into, and I will not enter into, any agreement which conflicts with this Agreement or that would, if performed by me, cause me to breach this Agreement. I further represent that I have no knowledge of any pending or threatened litigation to which the Company may become a party by virtue of my association with the Company. I further agree to immediately inform the Company of any such pending or threatened litigation should it come to my attention during the course of my employment. I also represent that I have provided to the Company for its inspection before I signed this Agreement all confidentiality, non-compete, non- solicitation, and all other employment-related agreements and obligations set forth herein. The Parties to which I am party to which I am bound.

11. Confidential Information of, and Agreements with, Former Employers. In the course of performing my duties to the Company, I will not utilize any trade secrets, proprietary or confidential information of or regarding any former employer or business affiliate in violation of any duty not to disclose or use such information, nor violate any written or oral, express or implied agreement with any former employer or other third party.

12. United States Government Obligations. I acknowledge that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to be bound by all such obligations and restrictions which are made known to me and to take all reasonable action to assist the Company in discharging the obligations of the Company under such agreements.

13. Remedies. I acknowledge that my failure to comply in all material respects with, or my material breach of, any of the terms and conditions of this Agreement shall irreparably harm the Company, and that money damages would not adequately compensate the Company for this harm. Accordingly, I acknowledge that in the event of a threatened or actual material breach by me of any provision of this Agreement, in addition to any other remedies the Company may have at law, the Company shall be entitled to seek equitable relief in the form of specific performance, temporary restraining order, temporary or permanent injunction or any other

equitable remedy then available, without requiring the Company to post any bond. I agree that nothing herein contained shall be construed as prohibiting the Company from pursuing any other remedies available to it for such threatened or actual breach, including money damages, and I agree that the Company shall be entitled to recover from me any attorney's fees it incurs in enforcing the terms of this Agreement.

14. Not an Employment Agreement. I acknowledge and agree that they are this Agreement is not relying upon a contract of employment for any representations specific period of time.

15. Miscellaneous.

(a) Reformation and Severability. If any provision of this Agreement is held to be invalid or statements made unenforceable under applicable law, such provision shall be reformed and/or construed, if possible, to be enforceable under applicable law; otherwise, such provision shall be excluded from this Agreement and the balance of the Agreement shall remain fully enforceable and valid in accordance with its terms.

(b) No Waiver. No delay or omission by the Company in exercising any right hereunder will operate as a waiver of that or any other Party right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other Party's employees, agents, representatives or occasion.

[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

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attorneys regarding(c) Reassignment. I expressly consent to be bound by the provisions of this Agreement except for the benefit of the Company or any subsidiary or affiliate thereof to whose employment I may be transferred, without the extent necessity that this Agreement be reassigned at

the time of such representations are expressly set forth herein. transfer.

14. (d) Governing Law. Applicable LawAny claim or controversy relating in any way to this . This Agreement shall be governed by and interpreted exclusively construed in accordance with the laws of the State of Delaware without regard (but not the law or principles of conflict of laws). The parties submit to the conflicts exclusive jurisdiction of law principles thereof. the state or federal courts of Delaware for all disputes arising out of or relating to this Agreement, and hereby waive, and agree not to assert, in any action, suit, or proceeding between the parties arising out of or relating to this Agreement that the action, suit, or proceeding may not be brought or is not maintainable in such courts, that this Agreement may not be enforced by such courts, that the action, suit, or proceeding is brought in an inconvenient forum, that the venue of the action, suit, or proceeding is improper, or that the action, suit, or proceeding, if brought in Delaware state court, may be removed to federal courts.

(e) Effective Date. This Agreement shall be effective as of the date of my Employment Agreement with the Company, shall be binding upon me, my heirs, executors, assigns and administrators, and shall inure to the benefit of the Company and its successors and assigns.

(f) Entire Agreement. This Agreement, together with my Employment Agreement with the Company, contains the entire agreement of the parties relating to the subject matter herein, and may not be waived, changed, extended or discharged except by an agreement in writing signed by both parties.

[SIGNATURES ON FOLLOWING PAGE; REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.(g) Acknowledgement. I acknowledge and agree that I have fully read and that I understand all of the terms and provisions of this Agreement, that I have had the opportunity to consult with an attorney and to discuss this Agreement with an attorney, that I have had any questions regarding the effect of this Agreement or the meaning of its terms answered to my satisfaction, and, intending to be legally bound hereby, I freely and voluntarily sign this Agreement.

ROCKWELL MEDICAL, INC.
IN WITNESS WHEREOF,

By: /s/ Russell H. Ellison, MD Name: Russell H. Ellison, MD
Title: President & CEO

EXECUTIVE

/s/ Megan C. Timmins
Megan C. Timmins Date July 29, 2021

EXHIBIT I

1. The following is a complete list of all inventions or improvements ("*Intellectual Property")* relevant to my employment by Rockwell Medical, Inc. (the "*Company*") that have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment by the Parties Company that I desire to remove from the operation of the Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-Competition Agreement between me and the Company (the "*Employee Agreement*").

☒No Intellectual Property.

☐Any and all Intellectual Property regarding:

☐Additional sheets attached.

2. I propose to bring to my employment the following materials and documents of a former employer or materials and documents created by me and/or others during any previous employment ("*Materials*"):

☒No Materials.

☐Materials:

☐Additional sheets attached.

3. I acknowledge and agree that the Materials set forth above are being provided by me in accordance with the representations set forth in Section 6 of the Employee Agreement between me and the Company.

/s/ Megan C. Timmins
Megan C. Timmins Date July 29, 2021

EXHIBIT C

SEPARATION AND RELEASE AGREEMENT

This Separation and Release Agreement (the "Agreement") is made between Rockwell Medical, Inc., a Delaware corporation (the "Company"), and Megan C. Timmins ("Executive", and together with the Company, the "Parties," and each a "Party"). Capitalized terms used but not defined herein shall have signed the meanings ascribed thereto in the Employment Agreement, dated as of July 16, 2021, by and between the Company and Executive (the "Employment Agreement").

1. Executive's employment ended, effective [, 20] (the "Separation Date"). Effective as of the Separation Date, Executive automatically resigned from any appointed or elected positions with any Released Party (as defined below), and Executive will cooperate with the Company to effectuate such resignations. The Company has provided Executive her accrued base salary through the Separation Date, and Executive is not owed any additional amount from any Released Party except as set forth herein.

2. Provided this Agreement has become effective, that Executive's representations set forth herein are accurate, and that Executive continues to abide by her obligations to the Company, the Company will provide Executive with the severance amounts and benefits set forth in Section 5(b) of the Employment Agreement (collectively, the "Severance Benefits") in accordance with the terms of the Employment Agreement.

3. Executive, on behalf of herself, her heirs, successors, assigns, and any individual or entity that could assert a claim through her or on her behalf relating to Executive's employment or termination of employment with the Company, fully and forever releases, acquits and discharges the "Released Parties" (defined as the Company, all of its past and present affiliates, parent companies, subsidiaries, investors, predecessors, successors, assigns, and related companies and entities, and all of their past and present shareholders, members, managers, partners, directors, officers, supervisors, trustees, employees, attorneys, persons and agents and all other persons and entities acting in connection with any of them) from and for all manner of claims, allegations, suits, charges, administrative actions, litigation and/or causes of action of any type, based upon any fact or set of facts, known or unknown, existing from the beginning of time through the date set forth below. this Agreement is signed by her (the "Released Claim(s)"). Without limitation and for illustration purposes only, the Released Claims include claims for or relating to: monetary damages and relief and/or recovery of every type; wrongful discharge; breach of express or implied contract, including regarding the Employment Agreement; any severance policy or plan; any incentive equity plan, policy or agreement; attorneys' fees and costs; retaliation, discrimination and/or harassment related to any protected characteristic or activity; Title VII of the Civil Rights Act, the Age Discrimination in Employment ("ADEA"), the Older Workers Benefit Protection Act, the Americans with Disabilities Act, and the Employee Retirement Income Security Act; and all other federal, state, common or local statutes, ordinances and laws. Notwithstanding the foregoing, Executive is not prohibited from making or asserting: (i) Executive's rights under this Agreement and any claims arising from the breach of this Agreement, the Employment Agreement or any equity award agreement by the Company, including any claim for breach of Company's obligation to make the payments described in Section 2 above; (ii) Executive's rights, if any, to indemnity pursuant to the Company's articles, bylaws, or any indemnification agreement between the

Baxter Healthcare Corporation

Company and Executive and/or to the protections of any director' and officers' liability policies of the Company and (iii) if Executive owns an equity interest in the Company, her rights as an equity owner.

4. The Parties intend that the general release by Executive will be construed as broadly as possible. Executive agrees not to commence or pursue any legal action regarding any Released Claims, provided that this Agreement does not limit her right, where applicable, to file or participate in an investigative proceeding of any federal, state or local governmental agency. To the extent permitted by law, Executive agrees that if such an administrative claim is made, she shall not be entitled to recovery of individual monetary relief or other individual remedies, provided that nothing in this Agreement limits her right to participate in the Securities and Exchange Commission's ("SEC") whistleblower program and receive a whistleblower's award thereunder. The Parties further acknowledge that the Company and its affiliates are not releasing any claims against Executive or any other individual, and all rights as to such claims are reserved.

5. Executive represents and warrants that: (a) she has returned all Company property, information and files in her possession, without retaining copies of same; (b) she has complied with the Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-

Competition Agreement between Executive and the Company dated as of July 16, 2021 (the "Restrictive Covenant Agreement"); and (c) she has not assigned any Released Claims.

6. Executive will cooperate with the Company in providing information with respect to all reports required to be filed by the Company with the SEC as they relate to required information with respect to her. Executive acknowledges and agrees that the Company may be required to file a copy of this Agreement with the SEC.

7. Executive acknowledges that she remains bound by, and will comply in all material respects with, her post-employment obligations to the Company, including but not limited to those set forth in the Employment Agreement and the Restrictive Covenant Agreement.

8. Executive acknowledges and agrees that pursuant to the requirements of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Section 954"), certain payments received by Executive may be subject to "clawback" in the event the Company is required to prepare an accounting restatement of its applicable financial statements due to the Company's material noncompliance with applicable financial reporting requirements. Executive agrees to promptly return to the Company the amount of any compensation paid to her that is required to be forfeited in accordance with Section 954.

9. Executive acknowledges that the Company's promises set forth throughout this Agreement would not be provided unless Executive executed this Agreement and are each separate and adequate consideration for this Agreement, including Executive's release of claims.

10. To the fullest extent permitted by law, and except as to statements made in legal, administrative or arbitral proceedings in disputes between Executive and the Company and truthful testimony, Executive agrees that she will not make public statements that defame, disparage or otherwise publicly speak of the Company or its present or former officers or members of the Board

By: _____

Name: _____

Title: _____

Date: _____

and/or its products or services in a false or misleading manner, including but not limited to through any media, social media, Facebook, Twitter or similar mechanism.

11. To the fullest extent permitted by law and at the sole expense of the Company, Executive agrees to reasonably cooperate with the Released Parties in any internal investigation, any administrative, regulatory or judicial proceeding or any dispute with a third party that she had knowledge of while employed by or providing services to the Company. Executive's cooperation may include being available to the Company upon reasonable notice and subject to Executive's personal and professional commitments, for interviews and factual investigations, appearing at the Company's request to give testimony without requiring service of a subpoena or other legal process, and turning over to the Company all relevant documents which are or may come into Executive's possession. If Executive is served with a subpoena or is required by court order or otherwise to testify or produce documents in any type of proceeding involving the Company or its affiliates, she must advise the Company within ten (10) days of same and reasonably cooperate with the Company in objecting to such request and/or seeking confidentiality protections.

12. This Agreement does not constitute an admission by the Company that any action it took with respect to Executive was wrongful, unlawful or in violation of any local, state, or federal act, statute, or constitution, or susceptible of inflicting any damages or injury on Executive, and the Company specifically denies any such wrongdoing or violation.

13. In addition to any other legal and/or equitable remedies, if Executive materially breaches any material provision of this Agreement, the Employment Agreement, the Restrictive Covenant Agreement, or any other contractual or legal obligation Executive owes to the Company, then the Company may cease paying and/or providing the Severance Benefits and Executive will be required to repay and/or forfeit any Severance Benefits received through the date of such breach or discovery of the inaccuracy of her representations, provided that Executive may retain $1,000 of such payments. The exercise of such remedies will not affect the validity of the release and other obligations of Executive as set forth in this Agreement or otherwise, nor will it limit the other legal and/or equitable remedies otherwise available to any Released Party.

14. This Agreement and the rights and obligations of the parties hereunder will be governed by, and construed and enforced in accordance with, the laws of the state of Delaware, excluding any such laws that direct the application of the laws of any other jurisdiction. The Released Parties are intended third party beneficiaries of Executive's obligations under this Agreement.

15. This Agreement will be enforceable to the fullest extent permitted by law. If any provision is held to be unenforceable, then such provision will be construed or revised in a manner so as to permit its enforceability to the fullest extent permitted by applicable law. If such provision cannot be reformed in that manner, such provision will be deemed to be severed from this Agreement, but every other provision of this Agreement will remain in full force and effect.

16. This Agreement may not be amended, modified, waived or terminated except in a writing signed by Executive and the Company's signatory to this Agreement or her successor. Further, the waiver by a party of a breach of any provision of this Agreement by the other will not operate or be construed as a waiver of any subsequent breach of the same or other provision of this Agreement.

17. Except as otherwise provided herein, this Agreement will be binding upon and inure to the benefit of the parties' respective successors, permitted assigns and transferees, personal representatives, heirs and estates, as the case may be; provided, however, that Executive's rights and obligations under this Agreement may not be assigned without the prior written consent of the Company.

18. Executive has had 21 calendar days to review and sign this Agreement and is advised to consult with an attorney of her choice before signing this Agreement, which includes a release of potential claims under the ADEA. Executive understands that she may use as much of this 21-day period as she wishes prior to signing. Changes to the Agreement, whether material or immaterial, will not restart the review period. Executive may expressly and voluntarily waive any part or all of the 21-day review period by signing and returning this Agreement prior to the expiration of the review period. Executive has the right to revoke her release of any and all ADEA claims by informing the Company of such revocation within seven calendar days following her execution of this Agreement (the "Revocation Period"); for the avoidance of doubt, no claims other than those arising under ADEA may be revoked during the Revocation Period. Any such revocation must be in writing and delivered to the Company in care of its signatory to this Agreement or her successor. This Agreement will become effective upon execution by Executive with respect to all claims other than those arising under ADEA, and will only become effective with respect to the release of ADEA claims if the Revocation Period has expired without any revocation having been delivered in writing to the Company within the Revocation Period. In the event that Executive revokes this Agreement with respect to ADEA claims, the Company shall make a single payment of $1,000, at which point Executive will be entitled to no further payments or severance benefits hereunder or under the Employment Agreement. Upon the expiration of the Revocation Period without the revocation of the ADEA claims, this Agreement shall be deemed to have become "final, binding and irrevocable," as set forth in Section 5(b) of the Employment Agreement.

19. This Agreement reflects the entire agreement of the parties relative to the subject matter hereof, and supersedes all prior, contemporaneous, oral or written understandings, agreements, statements, representations or promises regarding the subject matter hereof, provided that this Agreement does not supersede or modify the Employment Agreement, the Restrictive Covenant Agreement and those agreements pertaining to Executive's equity holdings.

20. This Agreement may be signed in counterparts, and when this Agreement has been signed by all parties, each counterpart shall constitute an original, notwithstanding that fewer than all of the parties' signatures appear on any one counterpart. An electronic signature transmitted by facsimile or other electronic means shall be deemed to be an original.

[Signature Page Follows]

The parties hereto confirm their agreement by the signatures shown below.

Rockwell Medical, Inc.

By:Name:

By: _____

Name: _____

Title: _____

Date: _____

[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

ATTACHMENT 1

Extended Accounts

[***]

[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

ATTACHMENT 2

3PL Accounts

[***]

[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

ATTACHMENT 3

Contract Price and Distribution Cost

[***]

Megan C. Timmins Date

Exhibit 10.31

ROCKWELL MEDICAL, INC.

AMENDED AND RESTATED
CLAWBACK POLICY
(THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. "POLICY")

Recoupment of Incentive-Based Compensation

It is the policy of Rockwell Medical, Inc. (the "Company") that, in the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws (including any such correction that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period), the Company will recover on a reasonably prompt basis the amount of any Incentive-Based Compensation Received by a Covered Executive during the Recovery Period that exceeds the amount that otherwise would have been Received had it been determined based on the restated financial statements.

Policy Administration and Definitions

This Policy is administered by the Compensation Committee (the "Committee") of the Company's Board of Directors, and is intended to comply with, and as applicable to be administered and interpreted consistent with, and subject to the exceptions set forth in, Listing Standard 5608 adopted by The Nasdaq Stock Market to implement Rule 10D-1 under the Securities Exchange Act of 1934, as amended (collectively, "Rule 10D-1").

For purposes of this Policy:

"Incentive-Based Compensation" means any compensation granted, earned, or vested based in whole or in part on the Company's attainment of a financial reporting measure that was Received by a person (i) on or after October 2, 2023 and after the person began service as a Covered Executive, and (ii) who served as a Covered Executive at any time during the performance period for the Incentive-Based Compensation. A financial reporting measure is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such a measure, and (ii) any measure based in whole or in part on the Company's stock price or total shareholder return.

Incentive-Based Compensation is deemed to be "Received" in the fiscal period during which the relevant financial reporting measure is attained, regardless of when the compensation is actually paid or awarded.

"Covered Executive" means any "executive officer" of the Company as defined under Rule 10D-1.

"Recovery Period" means the three completed fiscal years immediately preceding the date that the Company is required to prepare the accounting restatement described in this Policy, all as determined pursuant to Rule 10D-1, and any transition period of less than nine months that is within or immediately following such three fiscal years.

If the Committee determines the amount of Incentive-Based Compensation Received by a Covered Executive during a Recovery Period exceeds the amount that would have been Received if determined or calculated based on the Company's restated financial results, such excess

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ATTACHMENT 4

Settlement amount of Certain Non-Inventory Related Costs

[***]

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ATTACHMENT 5

New Exhibit C

Exhibit C

Support Services Incentive-Based Compensation shall be subject to recoupment by the Company pursuant to this Policy. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the Committee will determine the amount

based on a reasonable estimate of the effect of the accounting restatement on the relevant stock price or total shareholder return. In all cases, the calculation of the excess amount of Incentive-Based Compensation to be recovered will be determined without regard to any taxes paid with respect to such compensation. The Company will maintain and will provide to The Nasdaq Stock Market documentation of all determinations and actions taken in complying with this Policy. Any determinations made by the Committee under this Policy shall be final and binding on all affected individuals.

The Company will provide may effect any recovery pursuant to this Policy by requiring payment of such amount(s) to the services Company, by set-off, by reducing future compensation, or by such other means or combination of means as described below under the following terms and conditions for the benefit of the Distributor's efforts to Commercialize the Products.

Support Service

Support Services Committee determines to be provided include customer service ("Customer Service") appropriate. The Company need not recover the excess amount of Incentive-Based Compensation if and transportation/distribution service ("Transportation Services"), each as more fully described below.

Customer Service

Customer Service includes all services necessary to support customers the extent that the Committee determines that such recovery is impracticable, subject to and in accordance with any applicable exceptions under The Nasdaq Stock Market listing rules, and not required under Rule 10D-1, including if the ordering of Products through Committee determines that the fulfillment of Product orders, including fielding and resolving all inquiring and disputes related thereto. More specifically (and without limiting direct expense paid to a third party to assist in enforcing this Policy would exceed the foregoing), Customer Services include support related amount to order processing, order management, order fulfillment information technology, order fulfillment problem resolution, customer service inquiries related be recovered after making a reasonable attempt to orders and product use (including recover such amounts. The Company is authorized to take appropriate steps to implement this Policy with respect to mixer services), sales force support for new customer set up, general inquiries around customer order status Incentive-Based Compensation arrangements with Covered Executives.

Any right of recoupment or recovery pursuant to this Policy is in addition to, and technical service support deployment for Dri-Sate® Dry Acid Concentrate Mix System units (whether such units were installed prior to, on not in lieu of, any other remedies or after the Effective Date).

Transportation Service

Transportation Service includes all services necessary to ensure rights of recoupment that Products ordered by customers or the Distributor are delivered from the applicable Company manufacturing facility may be available to the applicable customer in accordance with Company pursuant to the applicable delivery instructions. More specifically (and without limiting terms of any other policy, any employment agreement or plan or award terms, and any other legal remedies available to the foregoing), Transportation Services include support related to distribution and delivery services including customer routing, shipments to customers and delivery of products within customer locations, as well as to fleet operations, hiring and instructing truck drivers, cross dock operations, transshipment costs to cross docking operations, facilitating local delivery, courier services, retaining, managing and paying third party freight carriers, supplying and paying for fuel, paying fleet management costs, obtaining insurance consistent with past practice of Company; provided that the Company filing and managing insurance claims and disputes, regulatory compliance in connection with Product transportation and overall transportation services management.

Dri-Sate® Dry Acid Concentrate Mix Systems (Mixer Services)

At the Distributor's request, the Company will (i) supply shall not recoup amounts pursuant to such other policy, terms or cause to be supplied technical services with respect to assisting customers with the Dri-Sate® Dry Acid Concentrate Mix Systems units for such units installed on or after the Effective Date and (ii) oversee and support training for the Distributor with such respect remedies to the Dri-Sate® Dry Acid Concentrate Mix Systems (the "Post-Transaction Mixer Services"). In addition, extent it is recovered pursuant to this Policy. The Company shall not indemnify any Covered Executive against the Company will supply or cause loss of any Incentive-Based Compensation pursuant to be supplied (at its sole cost and expense) technical services with respect to Dri-Sate® Dry Acid Concentrate Mix Systems units for such units installed prior to the Effective Date (the "~~Pre-~~this Policy.

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~~Transaction~~Pre-Transaction Mixer Services", together with This Policy amends and restates in its entirety the "Post-Transaction Mixer Services, the "Mixer Services").

Dedicated Resources

The Company commits to utilize the resources necessary to adequately fulfill customer orders and deliveries and to otherwise perform the Support Services, the Transportation Services and the Mixer Services (the "Services"). These resources will remain in place and dedicated to the Distributor's efforts to Commercialize Concentrate Products unless (i) significant changes occur around sales activity justifying a change, either increase or decrease, over the duration of the Services period and (ii) Distributor consents to such changes. Such changes will be communicated to the Distributor for approval no less than 10 days prior to taking effect.

Term of Services

The Services shall be provided by the Company until the expiration of the Transition Period.

Fees

[***] Company's Clawback Policy adopted March 23, 2017.

Consent to the Clawback Policy of
Rockwell Medical, Inc.

[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

ATTACHMENT 6

[***]

[***] CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Grantee:
Grant Date:
Number of Restricted Stock Units:

RESTRICTED STOCK UNIT AWARD AGREEMENT

THIS RESTRICTED STOCK UNIT AWARD AGREEMENT (the "Agreement" This agreement ("Agreement"), dated is made as of the grant date set forth above (the "Grant Date"), is made _____, 20__ by and between Rockwell Medical, Inc., a Delaware corporation (the "Company"), and (the individual set forth above, who is an employee of the Company (the "Grantee" "Executive"). Any capitalized terms used herein but not otherwise defined shall have the meaning set forth in the Company's 2018 Long Term Incentive Plan (the "Plan").

WHEREAS, the Plan was approved and adopted by the Company's Board of Directors (the "Board") and approved by the Company's shareholders at the Company's 2018 annual shareholder meeting and was amended and restated on each of May 18, 2020 and May 9, 2022 [and [May 23], 2023];

WHEREAS, the Company wishes to grant In exchange for any incentive compensation paid to the Grantee restricted stock units (the "Restricted Stock Units" or the "Award"), with each such unit representing the right to receive one share of its Common Stock (the "Common Stock"), pursuant to the terms and conditions of this Agreement and the Plan, the terms of which are incorporated by reference and made a part of this Agreement; and

WHEREAS, the Committee and the Board have determined that it would be in the best interest of the Company and its shareholders to grant the Restricted Stock Units provided for herein to the Grantee as an incentive for increased efforts during his or her service with the Company, or its

subsidiaries; have approved the grant of this Restricted Stock Unit Award on the Grant Date; and have advised the Company thereof and instructed the undersigned officer to execute this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants herein contained Executive and other good and valuable consideration, receipt of which is hereby acknowledged, the parties hereto do hereby agree as follows:

ARTICLE I

GRANT OF RESTRICTED STOCK UNITS

1.1. Grant of Restricted Stock Units. For good and valuable consideration, on and as 1. The Executive agrees to be bound fully by the terms of the Grant Date, the Company grants Company's Clawback Policy as in effect from time to the Grantee the number of Restricted Stock Units set forth above upon the terms and conditions set forth in this Agreement. The Restricted Stock Units shall vest and become non-forfeitable, in accordance with Section 3 hereof.time.

ARTICLE II

ADJUSTMENTS

2.1. Adjustments to Restricted Stock Units. 2. In the event it is determined by the Board of Directors of the Company (or a merger, statutory share exchange, reorganization, consolidation, recapitalization, dividend committee thereof) that compensation or distribution (whether in cash, shares or other property), a stock split, reverse stock split, spin-off or similar transaction or other change in corporate structure affecting sale proceeds must be reimbursed by the Common Stock or the value thereof, such adjustments and other substitutions shall be made Executive to the Restricted Stock Units as the Committee, in its sole discretion, deems equitable or appropriate, including adjustments in the number, class and kind of securities subject to this Restricted Stock Unit Award (including, if the Committee deems appropriate, the substitution of cash or other awards denominated in the shares of another company, or other property, as the Committee may

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determine to be appropriate in its sole discretion). Any of the foregoing adjustments may provide for the elimination of any fractional share.

ARTICLE III

VESTING AND FORFEITURE

3.1. Time-Based Restricted Stock Units. The Restricted Stock Units shall vest _____, so long as the Grantee is then continuing to serve as an employee through such dates (each, a "Vesting Date"). If the Grantee's service as an employee terminates prior to any Vesting Date, then the unvested portion of this Award shall terminate. Notwithstanding the above, the unvested portion of these Restricted Stock Units shall immediately vest if the Grantee ceases to be an employee due to the Grantee's death or disability occurring prior to the applicable Vesting Date.

3.2 Change in Control. Except as otherwise provided herein, upon a Change in Control, this Award shall be treated Company in accordance with the Clawback Policy, the Executive will promptly take any action necessary to effectuate such reimbursement.

3. The Clawback Policy applies notwithstanding the terms of Section 10.2 of any plan, policy or agreement under which compensation is granted or the Plan.

ARTICLE IV

OTHER TERMS OF RESTRICTED STOCK UNIT AWARD

4.1 Rights as a Shareholder. Grantee shall not be, nor have any of the rights or privileges of, a shareholder of the Company in respect terms of any shares of Common Stock underlying the Restricted Stock Units or any portion thereof, unless and until such Restricted Stock Units shall have Vested and been settled in accordance with the following sentence. As soon as practicable following the Vesting of any portion of this Award, and in no event later than March 15th of the calendar year following the calendar year in which the applicable Vesting Date occurs, a certificate or certificates representing such shares shall be issued by the Company to the Grantee, or a book entry representing such shares shall be made and such shares

shall be deposited with the appropriate registered book-entry custodian. The Company shall not be liable to the Grantee for damages relating to any delay in issuing shares or a stock certificate to Grantee, any loss of a certificate, or any mistakes or errors in the issuance of shares or a certificate to Grantee.

4.2 Dividends; Dividend Equivalents. Grantee shall not be entitled to receive any dividends or dividend equivalent rights with respect to unvested Restricted Stock Units.

4.3 Withholding. To the extent applicable, the Company shall have the right to withhold from Grantee's compensation or to require Grantee to remit sufficient funds to satisfy applicable withholding tax obligations upon the Vesting of the Restricted Stock Units. The Company shall be authorized to take any such action as may be necessary, in the opinion of the Company's counsel, to satisfy the Company's obligations for payment of such taxes. Such withholding shall be conducted through mandatory share withholding at minimum required amounts owed (or such higher amount elected by such Grantee as permitted by applicable law), unless prior to such Vesting, Grantee arranges for a cash payment of the applicable tax withholding to the Company; provided, however, that in the event such Vesting occurs during a Company blackout period, Grantee shall not be permitted to arrange for a cash payment of the applicable tax withholding.

ARTICLE V

MISCELLANEOUS

5.1. Award Not Transferable. Neither this Award of Restricted Stock Units, the shares of Common Stock subject to this Award of Restricted Stock Units nor any interest or right therein or any part thereof may be transferred, pledged, signed or otherwise alienated or hypothecated until termination

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of any restriction period and the issuance of shares of Common Stock in respect of any Vested Restricted Stock Units and any attempted disposition thereof shall be null and void and of no effect; provided, however, that this Section 5.1 shall not prevent transfers by will or by applicable laws of descent and distribution, or transfers agreement to which the Committee has given prior written consent, subject Executive is a party. This Agreement shall be deemed an amendment to any such agreement now in existence or executed in the future, in each case to the terms and conditions set forth in Section 11.3(a) of the Plan.

5.2 Notices. Any notice extent necessary to be given under the terms of this Agreement give full effect to the Company Clawback Policy.

4. Any amendments to the Clawback Policy after the date hereof, including any amendments to comply with applicable law or stock exchange requirement, shall be addressed applicable to the Company in care of its Secretary, and any notice to be given to the Grantee shall be addressed to him or her at the address stated in the Company's records. By notice given pursuant to this Section 5.2, either party may hereafter designate a different address for notices to be given to the party. Any notice, which is required to be given to the Grantee, shall, if the Grantee is then deceased, be given to the Grantee's personal representative if such representative has previously informed the Company of his or her status and address by written notice under this Section 5.2. Any notice shall have been deemed duly given when enclosed in a properly sealed envelope or wrapper addressed as aforesaid, deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service or when delivered personally to the Secretary or Grantee.

5.3. Amendment. Subject to Section 2.1 of this Agreement and Executive. If the terms of the Plan, Clawback Policy and this Agreement may only be amended by a writing executed by both conflict, the terms of the parties hereto if such an amendment would adversely affect the Grantee. Any such amendment Clawback Policy shall specifically state that it is amending this Agreement. prevail.

5.4. Governing Law. 5. The laws of the State of Delaware, without regard to its conflict of law provisions, shall govern the interpretation validity and performance validity of the terms provisions of this Agreement regardless of and all questions relating to this Agreement. This Agreement shall be binding on the law that might be applied under principles of conflicts of laws.

5.5 Plan Terms Control. Executive and his or her heirs, successors and legal representatives, and on the Company and its successors. In the event of that any conflict between the Plan and provision of this Agreement, or the terms application thereof, becomes or is declared by a court of

competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the Plan shall control, it being understood that variations parties hereto.

6. This Agreement sets forth the entire understanding of the parties and supersedes all prior agreements, arrangements, and other communications, whether oral or written, pertaining to the subject matter hereof; and, except as provided in paragraph 4 above, this Agreement from the terms set forth in the Plan shall not be considered to be in conflict if modified or amended except by written agreement of the Plan permits such variations. Company and the Executive.

5.6 Clawback Policy. This Agreement, the Restricted Stock Units and any economic benefits recognized by Grantee in connection with the Restricted Stock Units are subject to the Company's Clawback Policy as provided in the Company's Principles of Corporate Governance, which may be amended from time to time.

IN WITNESS WHEREOF, the parties Company and the Executive have executed this Agreement to be effective as of the Grant Date. day and year first above written.

_____ ROCKWELL MEDICAL, INC.
[Name of Executive]

By:
Name:
Title:

Exhibit 10.32

ROCKWELL MEDICAL, INC.

By:_____

Name: Mark Strobeck
Title: President & CEO AMENDED AND RESTATED STATEMENT OF COMPANY POLICY PROHIBITING INSIDER TRADING

GRANTEE:
_____

Grantee:
Grant Date:
Number of Restricted Stock Units:

RESTRICTED STOCK UNIT AWARD AGREEMENT

THIS RESTRICTED STOCK UNIT AWARD AGREEMENT (the "Agreement"), dated as of Because the grant date set forth above (the "Grant Date"), is made by and between common stock of Rockwell Medical, Inc., a Delaware corporation (the "Company"), is publicly traded on the NASDAQ, there are certain important restrictions and limitations imposed on you under the individual set forth above, who is federal securities laws. Any violation of these restrictions may subject the Company and you to serious criminal and civil liabilities and sanctions. Such a director violation would also severely damage the Company's reputation and business relationships. **This Policy applies to all personnel at every level of the Company and any of its subsidiaries.**

Prohibition against Trading on or Disclosing Material Nonpublic Information. It is the policy of the Company that all employees, officers and directors, and other persons that the Company may also determine should be subject to this Policy, such as contractors or consultants who have access to material nonpublic information (such persons, together with employees, officers and directors, "Company Personnel") who become aware of any material information relating to the Company that has not been made available to the general public by press release or otherwise, as well as their immediate family members, other individuals in their household, and any family members who do not live in their household but whose transactions in Company securities are directed by them or are subject to their influence or control ("Family Members"), and corporations or other business entities controlled or managed by such persons, and trusts or other entities for which any such person is the trustee or in which any such person has a beneficial or pecuniary interest ("Controlled Entities," and together with Company Personnel and Family Members, "Insiders"), are prohibited from purchasing, selling, gifting, or otherwise trading Company stock. In addition, Insiders may not convey material nonpublic information about the Company to others, or suggest that anyone purchase, sell, gift, or otherwise trade any the Company's securities while aware of material nonpublic information.

Material information may include, without limitation, changes in control or sale of all or part of the Company's business, a potential acquisition of another business or property, the opening of a new facility, a potential change in management, auditors, or the board of directors, internal financial information, extraordinary borrowing or liquidity problems, changes in dividend policies or the declaration of a stock split or the proposed or contemplated issuance, redemption, or repurchase of securities, a potential significant new customer contract (or loss of an existing significant customer contract), a new potentially significant cybersecurity risk or cybersecurity incident, major environmental incidents, the interruption of aspects of a company's business as a result of accident, fire, natural disaster, or breakdown of labor negotiations or any major shutdown, a material development in the FDA approval process, institution of, or developments in, major litigation, investigations, or regulatory actions or proceedings, or an important financing transaction. This list is merely illustrative. Any information, positive or negative, which might affect the Company's stock price or otherwise might be of significance to an investor in determining whether to purchase, sell or hold the Company's stock should be considered "material." Nonpublic information is information that is not generally known or available to the public. We consider information to be available to the public only when it has been released to the public by the Company through appropriate channels (e.g., by means of a press release, a filing with the SEC or a widely disseminated statement from a senior officer) and enough time has elapsed to permit the investment market to absorb and evaluate the information. As a general rule, you should consider information to be nonpublic until two full trading days have lapsed following public disclosure. The fact that rumors, speculation, or statements attributed to unidentified sources are public is insufficient to be considered widely disseminated even when the information is accurate.

For purposes of this Policy, references to "trading" and "transactions" includes, among other things: purchases and sales of Company securities in public markets; sales of Company securities obtained through the exercise of employee stock options granted by the Company; making gifts of Company securities; and using Company securities to secure a loan. Conversely, references to "trading" and "transactions" do not include: the exercise of Company stock options if no shares are to be sold or if there is a "net exercise" (e.g., where the Company withholds shares to satisfy tax obligations); the vesting of Company stock options or the delivery of shares upon vesting/settlement of restricted stock and/or restricted stock units; transferring shares to an entity that does not involve a change in the

beneficial ownership of the shares (for example, transferring shares from one brokerage account to another brokerage that you control); sales of the Company's securities as a selling stockholder in a registered public offering, including a "synthetic secondary" offering, in accordance with applicable securities laws; and any other purchase of Company securities from the Company or sales of Company securities to the Company in accordance with applicable securities and state laws. In addition, transactions in mutual funds that are invested in Company securities are not transactions subject to this Policy as long as (i) the Insider does not control the investment decisions on individual stocks within the fund or portfolio and (ii) Company securities do not represent a substantial portion of the assets of the fund or portfolio.

"Restricted Persons" of the Company, which includes directors, officers and employees who regularly have access to material non-public information as part of their job duties , as well as their Family Members and Controlled Entities, are subject to blackout periods during which no trading in the Company's securities is permitted. Such blackout periods are in effect during the period beginning at the close of the market fifteen (15) calendar days prior to the end each fiscal quarter and ending at the close of business on the second trading day following the date the Company's financial results for such fiscal quarter are publicly disclosed. From time to time, other types of material non-public information regarding the Company (such as negotiation of mergers, acquisitions or dispositions or new product developments) may be pending and not be publicly disclosed. While such material non-public information is pending, the Company may impose special blackout periods during which Restricted Persons and others are prohibited from trading in the Company's securities. If the Company imposes a special blackout period, it will notify the affected Company Personnel. These trading restrictions do not apply to transactions executed under a written trading plan in accordance with Rule 10b5-1 and our 10b5-1 Plan Parameters (a "10b5-1 Plan") that is approved by the General Counsel. Such 10b5-1 Plans must be pre-cleared in accordance with the procedures described below. The Company's 10b5-1 Plan Parameters are attached hereto as Exhibit A.

The period of time in between blackout periods is called a trading window. Because Restricted Persons are likely to obtain material non-public information on a regular basis, the Company requires all such persons to refrain from trading or establishing, modifying, or terminating a 10b5-1 Plan, *even during a trading*

window, without first pre-clearing all transactions (including a purchase, sale, or gift) in the Company's securities with the General Counsel (or, in the case of the General Counsel, the Chief Executive Officer) using a Preclearance Request form. All Preclearance Request Forms must be submitted at least two business days in advance of the proposed transaction. If a transaction is approved, the transaction must be executed by the end of the second full trading day after the approval is obtained, but regardless may not be executed if the Restricted Person acquires material nonpublic information concerning the Company during that time. If a transaction is not completed within the period described above, the transaction must be approved again before it may be executed.

Certain transactions in the Company' securities are prohibited, even during a trading window. Restricted Persons may not engage in short-term trading (generally defined as selling Company securities within six months following a purchase); sell the Company's securities short; buy or sell puts or calls or other derivative securities on the Company's securities; hold Company securities in a margin account or pledge Company securities as collateral for a loan; or enter into hedging or monetization transactions or similar arrangements with respect to Company securities.

It is also the policy of the Company that Insiders who become aware of any material nonpublic information in the course of their employment, service or relationship with the Company relating to any other company, such as the Company's customers, may not trade in that company's securities, convey such information to others, or suggest that anyone purchase, sell, gift, or otherwise trade in that company's securities, until the information becomes public or is no longer material.

From time to time, the Company may engage in transactions in its own securities. It is the Company's policy to comply with all applicable securities and state laws (including appropriate approvals by the Board of Directors or appropriate committee, if required) when engaging in transactions in Company securities.

Exhibit 10.32

Confidentiality. It is the policy of the Company that all Insiders must keep strictly confidential all material nonpublic information that such persons learn regarding the Company (and all material nonpublic information that such persons learn in the course of their employment, service, or relationship with the Company relating to any other company).

Employees who violate this Policy may be subject to disciplinary action by the Company, up to and including dismissal for cause. Any exceptions to the Policy, if permitted, may only be granted by the Compliance Officer (currently, the General Counsel) and must be provided before any activity contrary to the above requirements takes place.

All Company Personnel will be required to certify their understanding of and intent to comply with this Policy periodically.

This Policy will continue to apply to an Insider's transactions in Company securities after employment, service, or relationship with the Company has terminated until such time as you are no longer aware of material nonpublic information or until that information has been publicly disclosed or is no longer material.

If you have any doubts as to your responsibilities under this Policy, seek clarification and guidance from the General Counsel, **before you act**. Do not try to resolve uncertainties on your own. **Rockwell Medical, Inc. expects the strictest compliance with these procedures by all personnel at every level.**

Exhibit 10.32

ACKNOWLEDGEMENT AND CERTIFICATION

I certify that:

1. I have read and understand the Amended and Restated Statement of Company Policy Prohibiting Insider Trading (the "Grantee" "Policy") of Rockwell Medical, Inc. (the "Company"). Any capitalized

2. I understand that the General Counsel is available to answer any questions I have regarding the Policy.

3. Since the date the Policy became effective, or such shorter period of time that I have been with the Company, I have complied with the Policy.

4. I will continue to comply with the Policy for as long as I am subject to the Policy.

_____ _____

Signature Date

_____

Name (Please Print)

Exhibit 10.32

Rockwell Medical, Inc. 10b5-1 Plan Parameters

Capitalized terms used herein but not otherwise defined shall in these 10b5-1 Plan Parameters without definition have the meaning set forth in the Company's 2018 Long Term Incentive Plan Amended and Restated Statement of Company Policy Prohibiting Insider Trading (the "Plan" "Policy") of Rockwell Medical, Inc. (the "Company").

WHEREAS,

Entry Into a 10b5-1 Plan

- Requires preclearance under the Policy.
- Preclearance Request Forms must be submitted at least two business days in advance.
- Must occur during the trading window (if applicable to the Insider) and when the Insider is not in possession of material nonpublic information.
- Requires approval of the 10b5-1 Plan was approved and document by the General Counsel (or, in the case of the General Counsel, the Chief Executive Officer).

Instructions

- Any 10b5-1 Plan adopted by any Insider must be in writing, signed, and either:
  - specify the Company's Board amount, price and date of Directors (the "Board") and approved by the Company's shareholders at the Company's 2018 annual shareholder meeting ("Annual Meeting"); sales (or purchases) of Company securities to be effected;

WHEREAS, o provide a formula, algorithm or computer program for determining when to sell (or purchase) the Company wishes securities, the quantity to grant to the Grantee restricted stock units (the "Restricted Stock Units" or the "Award"), with each such unit representing the right to receive one share of its Common Stock (the "Common Stock"), pursuant to the terms and conditions of this Agreement sell (or purchase) and the Plan, the terms of which are incorporated by reference and made price; or

  - o delegate decision-making authority with regard to these transactions to a part of this Agreement; and

WHEREAS, the Committee and the Board have determined that it would be in the best interest of the Company and its shareholders to grant the Restricted Stock Units provided for herein to the Grantee as an incentive for increased efforts during his broker or her service with other agent without any material nonpublic information about the Company or its subsidiaries; have approved securities.

- For the grant avoidance of this Restricted Stock Unit Award on the Grant Date; and have advised the Company thereof and instructed the undersigned officer doubt, Insiders may not subsequently influence how, when, or whether to execute this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants herein contained and other good and valuable consideration, receipt of which is hereby acknowledged, the parties hereto do hereby agree as follows:

ARTICLE I

GRANT OF RESTRICTED STOCK UNITS

1.1. Grant of Restricted Stock Units. For good and valuable consideration, on and as of the date hereof, the Company grants effect purchases or sales with respect to the Grantee the number of Restricted Stock Units set forth above upon the terms and conditions set forth in this Agreement. The Restricted Stock Units shall vest and become non-forfeitable, in accordance with Section 3 hereof.

ARTICLE II

ADJUSTMENTS

2.1. Adjustments to Restricted Stock. In the event of a merger, statutory share exchange, reorganization, consolidation, recapitalization, dividend or distribution (whether in cash, shares or property), a stock split, reverse stock split, spin-off or similar transaction or other change in corporate structure affecting the Common Stock or the value thereof, such adjustments and other substitutions shall be made to the Restricted Stock Unit as the Committee, in its sole discretion, deems equitable or appropriate, including adjustments in the number, class and kind of securities subject to this Restricted Stock Unit Award (including, if an approved and adopted 10b5-1 Plan.

No Hedging

- Insiders may not have entered into or altered a corresponding or hedging transaction or position with respect to the Committee deems appropriate, securities subject to the substitution 10b5-1 Plan and must agree not to enter into any such transaction while the 10b5-1 Plan is in effect.

Good Faith Requirements

- Insiders must enter into the 10b5-1 Plan in good faith and not as part of cash a plan or other awards denominated scheme to evade the prohibitions of Rules 10b-5 and 10b5-1 under the Securities Exchange Act of 1934 (the "Exchange Act").
- Insiders must act in good faith with respect to the shares 10b5-1 Plan for the entirety of another company, its duration.

Certification Requirements

- Directors and officers (as defined in Rule 16a-1(f) under the Exchange Act, as amended, "Section 16 Officers," and together with directors, "Section 16 Persons") and their Family Members and Controlled Entities that enter into 10b5-1 Plans must certify that they are: (1) not aware of any material nonpublic information about the Company or other property, as the Committee may determine to be appropriate in its sole

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discretion). Any of Company securities; and (2) adopting the foregoing adjustments may provide for the elimination of any fractional share.

ARTICLE III

VESTING IN FORFEITURE

3.1. Time-Based Restricted Stock Units. The Restricted Stock Units shall vest 100% on the first anniversary of the Grant Date, so long as the Grantee is then continuing to serve as a director through such date (the "Vesting Date"). If the Grantee's service as a director terminates prior to the Vesting Date, then this Award shall terminate 10b5-1 Plan in good faith and not be exercisable. Notwithstanding as part of a plan or scheme to evade the above, these Restricted Stock Units shall immediately vest if prohibitions of Rules 10b-5 and 10b5-1 under the Grantee ceases to be Exchange Act.

Cooling Off Period

- The first trade under a director due to 10b5-1 Plan may not occur until the Grantee's death or disability occurring prior to the Vesting Date. The Committee shall have the discretion to vest all or any portion expiration of the Award in the event the Grantee's service a cooling off period as a director terminates prior to the Vesting date. follows:
    - 3.2 o Change in Control. Except For Section 16 Persons (as well as otherwise provided herein, upon a Change in Control, this Award shall be treated in accordance with their Family Members and Controlled Entities), the terms later of Section 10.2 of (1) two business days following the Plan.

ARTICLE IV

OTHER TERMS OF RESTRICTED STOCK UNIT AWARD

4.1 Rights as a Shareholder. Grantee shall not be, nor have any of the rights or privileges of, a shareholder of the Company in respect of any shares of Common Stock, the Restricted Stock Units or any portion thereof, unless and until such Restricted Stock Units shall have Vested and a certificate or certificates representing such shares have been issued by the Company to the Grantee, or a book entry representing such shares has been made and such shares have been deposited with the appropriate registered book-entry custodian. The Company shall not be liable to the Grantee for damages relating to any delay in issuing shares or a stock certificate to Grantee, any loss of a certificate, or any mistakes or errors in the issuance of shares or a certificate to Grantee.

4.2 Dividends; Dividend Equivalence. Grantee shall not be entitled to receive any dividends or dividend equivalents rights with respect to unvested Restricted Stock Units.

4.3 Withholding. To the extent applicable, the Company shall have the right to withhold from Grantee's compensation or to require Grantee to remit sufficient funds to satisfy applicable withholding tax obligations upon the Vesting of the Restricted Stock Units. Subject to the limitations in Section 11.5 of the Plan and approval of the Board, the Grantee may, in order to fulfill the withholding obligation, make payment to the Company in any manner permitted under Section 11.5 of the Plan. The Company shall not withhold more shares than are necessary to meet the established withholding requirements of Federal, state and local obligations. The Company shall be authorized to take any such action as may be necessary, in the opinion filing of the Company's counsel, to satisfy Form 10-Q or Form 10-K for the Company's obligations for payment completed fiscal quarter in which the 10b5-1 Plan was adopted and (2) 90 calendar days after adoption of such taxes.

ARTICLE V

MISCELLANEOUS

5.1. Award Not Transferable. Neither the shares of Common Stock subject to this Award of Restricted Stock Units nor any interest or right therein or any part thereof may be transferred, pledged, signed or otherwise alienated or hypothecated until termination of any restriction period and the issuance of shares of Common Stock in respect of any Vested

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Restricted Stock Units and any attempted disposition thereof shall be null and void and of no effect; 10b5-1 Plan; provided, however, that this Section 5.1 the required cooling-off period shall not prevent transfers by will or by applicable laws of dissent and distribution, or transfers to which the Committee has given prior written consent, subject to the terms and conditions set forth in Section 11.3(a) no event exceed 120 days.

o For other Insiders, 30 calendar days after adoption of the 10b5-1 Plan.

5.2 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of its Secretary, and any notice to be given to the Grantee shall be addressed to him or her at the address stated in the Company's records. By notice given pursuant to this Section 5.2, either party may hereafter designate a different address for notices to be given to the party. Any notice, which is required to be given to the Grantee, shall, if the Grantee is then deceased, be given to the Grantee's personal representative if such representative has previously informed the Company of his or her status and address by written notice under this Section 5.2. Any notice shall have been deemed duly given when enclosed in a properly sealed envelope or wrapper addressed as aforesaid, deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service or when delivered personally to the Secretary or Grantee.

5.3. • Amendment As discussed further below, the cooling off period applies to certain 10b5-1 Plan modifications as well.

Overlapping Plans

- . Subject An Insider may not enter into overlapping 10b5-1 Plans (subject to Section 2.1 certain exceptions).
- Please consult the General Counsel with any questions regarding overlapping 10b5-1 Plans.

Single-Trade Plans

- An Insider may not enter into more than one 10b5-1 Plan designed to effect the open-market purchase or sale of this Agreement and the total amount of securities as a single transaction during any rolling 12-month period (subject to certain exceptions).
- A single-transaction plan is "designed to effect" the purchase or sale of securities as a single transaction when the terms of the Plan, this Agreement may only be amended by plan would, for practical purposes, directly or indirectly require execution in a writing executed by

both single transaction.

Modification

- Requires preclearance under the Policy;
- Must occur during a trading window (if applicable to the Insider) and when the Insider is not in possession of material nonpublic information;
- Must receive approval from the General Counsel under the Policy; and
- Any modification to the amount, price, or timing of the parties hereto if such an amendment would adversely affect purchase or sale of the Grantee. Any such amendment shall specifically state that it is amending this Agreement. securities underlying the 10b5-1 Plan will be deemed to be a termination of the current 10b5-1 Plan and creation of a new 10b5-1 Plan and will be subject to all requirements set forth above regarding the adoption of a new 10b5-1 Plan.

Termination

- Requires preclearance under the Policy.

5.4. • Governing Law. The laws of the State of Delaware shall govern the interpretation, validity and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws. Seller should discuss with personal legal advisor.

5.5 • Plan Terms Control. In the event of any conflict between the Plan and this Agreement, the terms of the Plan shall control, it being understood that variations in this Agreement Must receive approval from the terms set forth in General Counsel under the Plan shall not be considered to be in conflict if the Plan permits such variations. Policy.

5.6 • Clawback Policy. This Agreement, the Restricted Stock Units and any economic benefits recognized by Grantee in connection with the Restricted Stock Units are subject It is advisable to the Company's Clawback Policy as provided in the Company's Principles of Corporate Governance, which may be amended from time to time. terminate a 10b5-1 Plan only under extraordinary circumstances.

IN WITNESS WHEREOF, the parties have executed this Agreement to be effective as of the Grant Date.

ROCKWELL MEDICAL, INC.

By:_____

Name: Mark Strobeck
Title: President & CEO

GRANTEE:

_____

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S FIRM

We consent to the incorporation by reference in the Registration Statements of Rockwell Medical, Inc. and Subsidiaries on Form S-3 (Nos. 333-266135, 333-259923, 333-228437, 333-160710, 333-148601, 333-135872, and 333-273983) and Form S-8 (Nos. 333-266892, 333-238889, 333-237229, 333-227365, 333-204653, 333-196752, 333-189586, 333-182043, 333-176524, 333-169003, 333-160135, 333-153046, 333-146817, and 333-273985) of our report dated March 21, 2024, on our audit of the consolidated financial statements as of December 31, 2023 and for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 21, 2024.

/s/ EisnerAmper LLP

EISNERAMPER LLP
West Palm Beach, Florida
March 21, 2024

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Rockwell Medical Inc. and Subsidiaries (the "Company") on Form S-3 (Registration No. 333-266135, 333-259923, 333-228437, 333-160710, 333-148601, 333-135872 and 333-135872) 333-273983) and Form S-8 (Registration No. 333-266892, 333-238889, 333-237229, 333-227365, 333-204653, 333-196752, 333-189586, 333-182043, 333-176524, 333-169003, 333-160135, 333-153046, 333-146817 and 333-146817) 333-273985) of our report dated March 30, 2023 with respect to our audits audit of the consolidated financial statements of the Company as of December 31, 2022 and 2021, , and for each of the two years in the period year then ended, December 31, 2022, which report is included in this Annual Report on Form 10-K of the Company for the year ended December 31, 2022 December 31, 2023.

/s/ Marcum llp LLP

Marcum llp LLP
Chicago, IL
March 30, 2023 21, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Strobeck, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rockwell Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the

period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2023 21, 2024

/s/ Mark Strobeck

Mark Strobeck
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Rockwell Medical, Inc. (the "Company") for the year ended December 31, 2022 December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes Oxley Act of 2002, that to the best of his knowledge:

1. the Periodic Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated:
March 30, 2023 March 21, 2024

/s/ Mark Strobeck

Mark Strobeck
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Periodic Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Rockwell Medical, Inc. and will be retained by Rockwell Medical, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

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